



Radioactive Material License Guide for the Use of Accelerators to Produce Radioactive Material

North Dakota Department of Health
Division of Air Quality
Radiation Control Program
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NOTES

INTRODUCTION

This guide describes the type and extent of information needed by the Radiation Control Program to evaluate an application for a specific license for authorization to use accelerators to produce radioactive material. The applicant should carefully study the regulations and this guide, and submit all information requested. Omission of necessary information may delay the processing of the application. This guide does not substitute for understanding the requirements of the regulations.

The following portions of the North Dakota Radiological Health Rules apply and should be used in conjunction with this guide.

- A. Chapter 33-10-01 "General Provisions"
- B. Chapter 33-10-03 "Licensing of Radioactive Material"
- C. Chapter 33-10-04.1 "Standards for Protection Against Radiation"
- D. Chapter 33-10-09 "Radiation Safety Requirements for Particle Accelerators"
- E. Chapter 33-10-10 "Notices, Instruction and Reports to Workers-Inspections"
- F. Chapter 33-10-11 "Fees for Issuance of License and Registration Certificates and Inspections"
- G. Chapter 33-10-13, "Transportation of Radioactive Material"

In addition, No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration issued pursuant to chapter 33-10-02.

This guide is for general guidance in preparation of the license application and should not be considered as all the information that may be required for a particular application. Nor is it a substitute for the applicant's safety evaluation of the proposed activity. The applicant must ensure that the application correctly and adequately describes the commercial services offered, and the radiation safety measures and procedures to be followed in order to provide adequate protection. For the purposes of this guide, "accelerator" describes any cyclotron, betatron, electron linear, or potential-drop accelerator used to produce radioactive material.

For more information, please refer to Attachment No. 1, "Regulatory Considerations for the Monitoring of Emissions from Medical Radionuclide Producing Cyclotrons", by Markus Spivak and Sandra Hinkel of the New York State Department of Environmental Conservation. Also see Attachment No. 2 with regards to "PET Site Planning" – this document was developed by R.D, Hichwa at the University of Iowa College of Medicine.

It is the responsibility of the applicant to determine that all applicable permits (wastewater discharge, water runoff, air quality, etc.) are obtained before initiation of activities. Issuance of a Radioactive Material License does not imply that all requirements of the Department of Health have necessarily been met.

Any information submitted in an application becomes public record. Certain restricted kinds of information such as trade secrets, proprietary information, and commercial or business information may be held confidential. If this is desired a letter must be sent to the Division Director requesting confidentiality and setting forth reasons why the information may be confidential in accordance with

N.D. Century Code 23-20.1-09.1.

If a license must be renewed or amended, the compliance history of the licensee for which the renewal or amendment is sought will be considered prior to the issuance.

All information, including written statements, forms and drawings, submitted with the application become a part of the license and require an amendment of the license if they change.

FINANCIAL ASSURANCE ARRANGEMENTS

North Dakota Radiological Health Rules Chapter 33-10-03-05.14, contains requirements for licensees to post, with the Department, financial security to ensure the protection of the public health and safety and the environment in the event of abandonment, default, or other inability or unwillingness of the licensee to meet the requirements of the regulations. The applicant must review this regulation and provide information as necessary.

AS LOW AS REASONABLY ACHIEVABLE

The applicant should, in addition to complying with the requirements set forth in the North Dakota Radiological Health Rules, make every reasonable effort to maintain radiation exposures As Low As Reasonably Achievable (ALARA). Applicants should give consideration to the ALARA philosophy in the development of operating procedures and in the training of employees.

Management can contribute to maintaining low occupational exposures by reviewing personnel monitoring records, employee performance, and procedures to identify those areas where improvement may be achieved.

LICENSE FEES

Applications for amendment of existing licenses should be filed in the same manner as initial applications or may be filed in letter form. The application should clearly identify the license which is to be amended by license number. The exact nature of the requested changes should be specified and additional supporting information, as necessary, should be provided.

Licenses are normally issued for a period of five years. If an application for license renewal is filed thirty days or more before license expiration, the existing license remains in effect until the new application has been finally acted upon by the Department.

Renewal applications should be filed using form SFN 8418 and should contain complete and up-to-date information concerning the applicant's current program. References to previously submitted documents should be clear and specific and specify the document by date and indicate pertinent information by page and paragraph. There is no fee associated with the license renewal process.

FILING AN APPLICATION

The application (SFN 8414) should be completed following the instructions provided with the form. The signed original copy should be filed with the Department and one copy kept by the applicant. Supplemental information should be labeled to identify the applicant and should reference the item for which information is being given.

All items of the application should be completed in sufficient detail to allow the Department to make an accurate review of the program with regard to safe use of accelerators to produce radioactive material. Any section in the application that is not applicable should be designated with N/A.

Because the space on the application form is limited, attachments must be used. Clearly identify information submitted as an attachment; for example, "...see Attachment A, Page 5, Item C."

Mail the original application to: North Dakota Department of Health
Radiation Control Program
1200 Missouri Avenue, Box 5520
Bismarck, ND 58506-5520

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE (SFN-8414)

Item 1 - Applicant and Locations of Use: The applicant corporation or other legal entity should be specified by name and mailing address in Item 1(a). Individuals should be designated as the applicant only if they are acting in a private capacity and the use of radioactive material is not connected with their employment with a corporation or other legal entity.

The actual sites of use should be given in 1(b). Permanent facilities should be identified by room number, floor, building name, street address, city, and state. It is required that a licensee maintain a permanent in-state facility.

Attach additional sheets if more space is needed.

Item 2 – Self Explanatory

Item 3 Denote "New License Application," "Renewal," or "Amendment." If you are requesting a renewal or amendment, please provide your North Dakota Radioactive Material License Number. If you have a license with the U. S. Nuclear Regulatory Commission, another Agreement State or a Licensing State, please list these as well.

To prevent interruption of activities conducted under a license during renewal, the regulations require filing of renewal application 30 days before expiration. If the Department does not receive the required renewal request by this date, an application for a new license, along with the appropriate fee, may be required.

Item 4 Each person who will use radioactive material should be named and their qualifications provided as explained in Items 8 and 9.

Individuals who will be using the accelerator and accelerator produced radioactive material, or who will provide direct personal supervision of the use of the accelerator and accelerator produced radioactive material must be listed. Provide the qualifications and training (formal education and on-the-job) of all individuals in items 8 and 9 or in a separate attachment.

Individuals who will use the accelerator and accelerator produced radioactive material must be approved by the Radiation Safety Committee and designated by the RSO after they satisfactorily complete training in the safe handling of positron-emitting radioactive material and use of the accelerator.

Item 5 If multiple users will be listed in Item 4, a radiation safety officer should be named in Item 5. A statement should be included with the application outlining the duties and responsibilities of the RSO.

The radiation safety officer is expected to coordinate the safe use of the accelerator and accelerator produced radioactive material and to ensure compliance with the North Dakota Radiological Health Rules Chapter 33-10-01 through 33-10-14 and applicable Department of Transportation Regulations.

Typical duties of the radiation safety officer should include:

- A. To assure that radioactive materials possessed under the license conform to the materials listed on the license.
- B. To assure that use of the accelerator and accelerator produced radioactive material is only performed by individuals authorized by the license.
- C. To assure that all users wear personnel monitoring equipment, such as film badges, thermoluminescent dosimeters (TLD), or OSL badges when required.
- D. To assure that the accelerator and accelerator produced radioactive material are properly secured against unauthorized removal at all times when they are not under constant surveillance.
- E. To serve as a point of contact and give assistance in case of emergency (overexposure, spill, fire, theft, etc.) and assure that proper authorities, for example, local police, and this Department, are notified promptly in case of accident or damage to the accelerator or accelerator room.
- F. To assure that the terms and conditions of the license, such as periodic leak tests, and physical inventories are met and that the required records, such as personnel exposure records, leak test records, etc., are periodically reviewed for compliance with Department rules, requirements, and license conditions.

An Assistant RSO for accelerator operations should be named to represent radiation safety for the accelerator facility. He or she should be a full-time employee of the institution, be based on-site and be responsible for radiation safety during day-to-day operations at the accelerator facility. Provide the name(s) and contact information of the Assistant RSO for accelerator operations.

The RSO and Assistant RSO for accelerator operations must have the authority to act for and on behalf of the licensee. Verification of this authority must be included in the application.

Provide the qualifications and training (formal education and on-the-job) of the individuals designated as RSO and Assistant RSO for accelerator operations in Items 8 and 9.

Item 6a Identify each radioisotope by element name and mass number that will be produced by the accelerator (e.g., ^{11}C , ^{18}F). List significant collateral nuclides based on nominal production parameters.

Item 6b For each radioisotope listed in item 6a, describe the chemical and/or physical form (e.g., ^{18}F -FDG) and maximum quantity of each radioisotope that the licensee will possess, use and store at any one time.

Item 7 Describe the type of accelerator, including manufacturer name, model, energy range, beam uniformity, irradiation time, and chemistry of the target and product.

Specify the purpose for which the licensing of material in item 6 is requested. If used in a device, give the make and model number of the device. If used to produce radioactive material for research or commercial distribution, please specify.

Item 8 & 9 The training and/or experience of each person who will directly supervise the use of the accelerator and accelerator produced radioactive material and/or who will have radiological safety responsibilities should be submitted as indicated in Items 4 and 5 above.

The qualifications of users and radiation safety personnel should be commensurate with the proposed use.

An authorized individual user, specified on the license, must be present and directly supervise use of

the accelerator and accelerator produced radioactive material.

If the applicant desires to provide in-house training for their own personnel, a description of the training must be provided. Included in the description of in-house training should be:

- A. The name(s), training and experience of the individual(s) providing formal training.
- B. An outline of the formal training and on-the-job training to be provided, including the duration of the training.
- C. The means of determining when the trainee has satisfactorily completed the training and is capable of carrying out the radiation safety responsibilities required by the license.

A qualified expert must be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation and before routine operation. A qualified expert must also perform a radiation survey after changes in shielding or major changes in occupancy of surrounding areas, operations, etc. The qualified expert should have the following training and experience:

- A. A bachelor's degree, a master's degree or a doctorate in radiological physics or a closely related field such as physics or health physics; and who has participated in the design and radiation survey of at least two facilities which are similar in design complexity, intended uses and beam characteristics (including energies), and who has had primary responsibility for the design and radiation survey of at least one similar facility.
- B. The design experience described above must have included calculation and specification of shielding requirements; design and layout of any ancillary equipment such as hot cells and radionuclide handling and transport systems; and design of monitoring, warning and safety systems.

Submit the training and experience of the qualified expert who will or has consulted on the design of your installation and approved it. Submit a copy of that approval.

Items 10 and 11 A radiation survey instrument is required when using an accelerator and accelerator produced radioactive material. The survey instrument(s) that will be available at each site where the accelerator and accelerator produced radioactive materials are used should be specified. These instruments must be capable of measuring alpha, beta, gamma, neutron and positron radiation so that complete and adequate surveys of public dose levels and contamination may be conducted. The facility must have capabilities for measuring airborne radioactivity in work areas and public areas.

For each type of radiation detection instrument available to the program, the applicant must specify the manufacturer's name and model number, the number of instruments available, the type of radiation detected and the range in microrentgens or milliroentgens per hour or counts per minute. Confirm that the radiation detection instrument will be capable of detecting each radionuclide produced by the accelerator.

An adequate calibration of survey instruments usually cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.

Daily or other frequent checks of survey instrument function should be supplemented every 12 months with a two-point calibration on each scale of each instrument with the two points separated by at least

50 percent of the maximum scale divisions. Survey instruments should also be calibrated following repair. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for the points checked. Readings within ± 20 percent are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

The description of applicant's calibration procedures should include, as a minimum:

- A. The manufacturer and model number of each radiation source to be used,
- B. The nuclide and quantity of radioactive material contained in the source,
- C. The accuracy of the source(s). The traceability of the source to a primary standard should be provided,
- D. The step-by-step procedures for calibration, including associated radiation safety procedures, and
- E. The name(s) and pertinent experience of person(s) who will perform the calibrations.

If instrument calibration will be performed by an organization other than the applicant, the name of the organization should be included in the application.

Item 12 Personnel who will be using, or directly supervising the use of the accelerator or accelerator produced radioactive material are required to wear personnel monitoring devices such as film badges, thermoluminescent dosimeters (TLD) or other approved personal monitoring devices. Specify the type of device, the frequency of exchange and the name and address of the service provider. Confirm that the personnel monitoring devices will accurately measure each type of radiation present (i.e., gamma, positron, neutron, etc.).

Ring or wrist badges may be necessary for certain personnel who may received substantial radiation doses to their extremities, such as from maintenance activities or due to the handling of radioactive materials.

Item 13 Describe the facility, including a drawing showing the location of equipment and accelerator use activities. The description should include facility design and dimensions and should show the location of restricted areas.

A. Scaled drawings of the facility should include, at a minimum, the following areas:

- 1. Location of the accelerator within the building;
- 2. Diagram of the accelerator and associated rooms;
- 3. Diagrams of the room associated with radioactive material production or use;
- 4. Locations of all area monitors, ventilation equipment (e.g., vents, filters) and other equipment and fixtures;
- 5. Receipt, use and storage areas for radioactive material;
- 6. Location of hot lab(s) within the facility;

7. Diagrams of each hot lab identifying location of equipment, shielding and fixtures;
8. Location of equipment cooling systems;
9. Ventilation system room layout, including location of ducts, exhausts and intakes;
10. Rooftop diagram for air intakes and exhausts;
11. Radioactive material waste storage and handling areas;
12. Radioactive material packaging and transport areas;
13. Associated mechanical equipment rooms, including locations of vents, stack penetrations and filters; and
14. Unrestricted areas above, below or adjacent to areas where radioactive materials are produced, stored, or used.

Illustrations for each room and major areas should be provided as well as plan drawings for each floor and two orthogonal elevation drawings for the entire facility.

Area restrictions should be illustrated on each drawing as appropriate. Locations where radiation field and contamination surveys will be performed routinely should be clearly marked.

B. Illustrations of systems within the facility, to include:

1. The accelerator and direct attachments, including beam piping, power supplies, magnets and related equipment, exclusive of target devices.
2. Target systems, including controls, monitors, piping, mounting and demounting mechanisms, containment, shielding and interfaces with transport systems. For commercial production, separate illustrations for each product system should be provided.
3. Shielded work areas for target handling, processing, assaying and packaging, including manipulators, process equipment, containment, shielding, piping, other controls, monitors and local filters. For commercial production, separate illustrations for each product system should be provided.
4. Ventilation (heating, ventilation, air-conditioning) equipment and systems including fans, ducts, exhausts, intakes, controls, monitors and filters.
5. Accelerator and target cooling systems to include pumps, piping, supplies, isolation valves or devices, drains, controls, monitors and filters.
6. Vacuum systems to include pumps, piping, intakes, exhausts, controls, isolation valves or devices, monitors and filters.
7. Dedicated gas exhaust or special liquid handling systems, including drains (e.g., glove boxes, fume hoods), showing areas evacuated or drained, piping, pumps, controls, filters and exhausts. Generally, no connections to other systems should be made and this should be clearly illustrated where systems are in close proximity.

8. Transport systems for radioactive material (automatic, remote control or pneumatic systems for targets, radiopharmaceuticals, etc.) Drawings should show each station and location, all routes, typical hardware for routes, stations and carriers, and controls and monitors.
9. Interlock systems, showing installed locations, controls, readouts and warning devices, and areas protected.
10. Area radiation monitoring systems, including installed locations and areas to be monitored, typical sensor and read-out hardware and controls and calibration devices. Portal monitor and portable survey instrument locations should also be included.

Illustrations can be in the form of engineering line drawings, blueprints, perspective drawings, detailed manufacturer's literature (service manuals), or multiple views by industrial photography. Provided that enough detail is present for the Department to perform a safety evaluation of each system. Sales brochures or simple snapshots may not provide sufficient information.

C. Comprehensive descriptions of the use of each of the areas listed under letter A., above, including estimates of the amount of radioactive material, and the range of ambient radiation fields expected in each area during use of the accelerator and accelerator produced radioactive material. Access by authorized personnel should also be discussed. Areas designated as "clean areas" should be demarcated from those where contamination may be expected.

D. Descriptions, specifications and discussions of the operating principles and performance parameters of each of the systems under B., above. These should also include performance parameters as installed and how these were determined, logic of operation, trip points or set points for monitored parameters and how systems fail to a safe configuration with loss of power or loss of a major component (such as a fan, pump, cooling system or sensor).

For the ventilation system, the final design and installation should be reviewed by an individual with experience in radiation safety. This individual's credentials should be submitted with the information described above.

Item 14 Radiation Protection Program

See Appendix A entitled, "Radiation Safety Procedures and Description of the Radiation Safety Program"

Item 15 Waste Disposal - Indicate who will handle the disposal of radioactive waste. See Section XVI of Appendix A, entitled, "Radioactive Waste". Records of transfer and disposal must be maintained in accordance with the North Dakota Radiological Health Rules. A method of disposal other than transfer to an authorized recipient must be described in detail and will be authorized on a case by case basis.

Transportation of accelerator produced radioactive material shall be in accordance with North Dakota Radiological Health Rules Chapter 33-10-13 and with applicable sections of the U.S. Department of Transportation (DOT) regulations contained in 49 CFR Parts 170 - 189.

Item 16 Read the certification statement and complete this section by entering the name, company affiliation and contact information of the applicant. The entire application should be reviewed and signed by a high-level management official within the company, such as a president or CEO. The main contact person for the license should be the RSO.

Appendix A

Radiation Safety Procedures and Description of the Radiation Safety Program

I. Administration of Program

A. Radiation Safety Program Management and Radiation Safety Officer (RSO) authority, duties and responsibilities.

Provide an institution organizational chart which includes the RSO and the positions superior to the RSO; and fully describe the lines of communication and authority. Discuss how authority and responsibilities are delegated through this structure from the Chief Executive Officer to the RSO.

Discuss the appointment of the RSO and an Assistant RSO for accelerator operations, including minimum qualifications, process for appointment and concurrences required.

Confirm that the RSO and Assistant RSO for accelerator operations has sufficient authority to halt operations, restrict areas, and detain employees or others at the facility for decontamination if, in his or her judgment, such actions are appropriate.

Describe duties and responsibilities for the Assistant RSO for accelerator operations. This individual should be assigned to the accelerator facility, but should not be directly involved in production or experimental work that would conflict with his or her duties to assure safety.

Describe how the responsibilities of the RSO and Assistant RSO for accelerator operations are implemented to assure that radiation safety is integrated into the program. Indicate procedures to accomplish each of the following and designate the individuals or staff positions at the accelerator facility who will be responsible for each task.

Responsibilities for radiation safety should include:

1. Inventory and control of radioactive sources, targets and other activated materials;
2. Observation and control of radiation hazards;
3. Radioactive waste storage and disposal;
4. General radiation monitoring procedures;
5. Instruction of personnel in observation of rules and monitoring procedures;
6. Maintenance of records related to exposures and accumulated doses received by the personnel;
7. Periodic routine surveys of the accelerator installation;
8. Surveys of new experimental setups;

9. Survey of unusual conditions including conditions during maintenance operations; and
10. Environmental monitoring and assessment of releases.

B. Radiation Safety Committee for accelerator operations

A local committee should be established to oversee accelerator operations. It should be composed of key staff at the accelerator facility and expert advisors on radiation safety.

The Radiation Safety Committee of any institutionally related broad or specific license is not necessarily appropriate or useful in this regard (since few of its members may have any direct knowledge or concern with accelerator operations). Describe the applicable safety committee in terms of:

1. Membership and general qualifications;
2. Duties and responsibilities;
3. Frequency of meetings; and
4. Method of recording minutes.

The membership of this committee should be communicated to the Department initially, but when individual changes are made later, which are within the guidelines established in B.1., above, these need not be communicated to the Department.

C. Radiation Safety Officer (RSO) qualifications

1. Radiation Safety

Describe his or her comprehensive training and experience related to radiation safety for use and maintenance of accelerators capable of producing radioactive material in significant quantities. Additionally, describe training in mechanical and electrical safety related to:

- a. Beam transport and high vacuum systems;
- b. Target systems and target containment systems;
- c. Auxiliary mechanical equipment;
- d. Special fire protection; and
- e. Control systems.

2. Training

Indicate areas of expertise which demonstrate his or her ability to train operators and technicians in specific problems for the accelerator and to provide information about radiation safety and special hazards relating to use of this

accelerator. (See also below and Section XI for scope of training to be authorized.) If accelerator operator training is to be conducted by facility management instead, provide similar information.

3. Independent expertise

The RSO should be independent of production or operations management for the facility, but must be equally well trained in operations in order to perform effective audits. Indicate how this independence and equivalent training is to be accomplished and preserved.

D. Staffing patterns and authorized users of the accelerator and radioactive material

1. Describe the organization of the facility staff with a chart and a narrative explanation. Indicate which staff positions will perform irradiations, target and material transfers and radiochemical processing.
2. Describe how the staff positions directly involved with the handling of radioactive material and/or operating the accelerator will be supervised.
3. Describe the minimum shift complement in terms of staff positions, for each major type of operation, including:
 - a. Bombardment for commercial products;
 - b. Bombardment for experimental runs;
 - c. Operations involving target handling;
 - d. Processing radiochemicals and commercial product manufacturing, packaging and quality control; and
 - e. Manufacturing control, packaging and labeling.
4. Indicate who must be on call for emergencies, for each type of operation, in terms of staffing positions.

Note: For training and experience requirements for other individuals or staff positions, see Section XI.

E. Scheduling and control

Discuss the mechanisms for scheduling users, production runs, experiments and maintenance. (See also Section V.D. on surveys to determine acceptable times for production activities and for maintenance activities.) Discuss what protocols will be followed and what notification of scheduling will be provided. Show how your system will provide at least 24 hours advance notice in writing to all affected accelerator personnel.

F. Area restriction

Discuss restriction of areas in the facility during the production of commercial products or radiopharmaceuticals. Also discuss security of areas within the facility and the facility

as a whole, when unattended, or during off duty hours. (See also Section V on surveys.)

G. General authorization and evaluation of experiments

For the general authorization for radioactive material for research and development discuss the evaluation of experiments and how decisions are made regarding area restriction. Submit a formal review policy to address:

1. The details of a given experiment and possible interaction of the hazards of equipment and materials with other operations.
2. The layout and design of experiments, with regard to confining and containing any potential accident to the smallest area.
3. Describe the individuals involved with this review and the documentation which is to be retained for inspection by the Department.

H. Internal Inspections, Audits and Reviews

Discuss in detail the formal program for on-going supervision and inspection of authorized users, facility and radiation safety program. At a minimum the following should be included.

1. Written guides and procedures for inspection;
2. Reports to users;
3. Schedules for inspections;
4. Assignment of personnel to perform inspections;
5. Schedules for review of reports; and
6. Follow-up and corrective action(s) for violations identified and escalated enforcement for repeat or flagrant violations.

I. Procedures and Precautions for Use of Radioactive Material in Animals

Describe procedures and precautions to be followed if radioactive material will be used in animals. Such procedures are described in Appendix H ("Considerations for Laboratory Animal and Veterinary Medicine Uses") of NUREG-1556, Volume 7, published by the U.S. Nuclear Regulatory Commission.

II. Operating Procedures, Radiation Hazards and Safety Considerations Descriptions to be included in a Radiation Safety Manual (submit your operating manuals).

A. Provide a description of the type and uses of the accelerator. Indicate the following:

1. Type of Accelerator;
2. The particles accelerated;

3. The energy of the accelerated particles;
 4. The type of targets that will be utilized;
 5. Geometry and shielding characteristics of the structural materials composing and surrounding the accelerator;
 6. Long-lived activity in the machine after extended runs;
 7. Time delay before the accelerator vault enclosure can be entered;
 8. Activation process (nuclear reaction scheme) for each product produced (commercial targets and radiopharmaceuticals); and
 9. The uses of the beam, including solid target irradiation, direct therapy, direct production of gases and liquids, etc.
- B. Standard operating and safety procedures for accelerator startup, standby modes, shutdown and target exchange as well as down times. These should include:
1. Area restriction;
 2. Steps for startup, standby and shutdown;
 3. Acceleration parameter adjustment/checking;
 4. Monitor checking (safety/production);
 5. Visual/aural surveillance over access routes/accelerator areas; and
 6. Minimum staffing patterns for various operational modes such as vault entry before irradiation, irradiation, standby, target handling, vault entry after irradiation, radioactive material (including target) processing.
- C. Describe procedures for mitigating the radiation hazards associated with the accelerator sources in your facility (See also Appendix B). Include in your written operating and safety manual the appropriate safety procedures for the following:
1. Hazards of the primary beam of particles accelerated and any collateral radiation (example: synchrotron-type radiation) from the primary beam while under acceleration or in drift tubes, and hazards of the beam at the exit ports.
 2. Scatter radiation produced when the primary beam strikes the target or other material. Describe auxiliary shielding materials used to absorb a beam which would otherwise strike metal components.
 3. X-rays produced at the target end of the machine, and also at the high-voltage terminal by the back-streaming of electrons (for potential drop devices).
 4. Neutrons produced by nuclear reactions in the target or other objects struck by the beam.
 5. Targets which are radioactive before radiation, due to recycled feedstocks or

other causes.

6. Target activity and other induced radioactivity, after the beam is turned off, from machine components and targets. Discuss the radiation hazards from the activation process both due to radiation fields and due to contamination. Containment systems for handling radioactive material should be included here.

In addressing the above areas, discuss targets in particular, but include vacuum chamber walls, electrode supports and other significant sources. Address safety, and submit procedures for personnel entering the room to perform maintenance, target changes, and routine or special adjustments. Specify radiation levels (as indicated by representative area monitors) for routine entry, levels requiring investigations and maximum levels for entry and/or occupancy, for each area.

7. Cooling water/other cooling media. Describe radiation safety for:
 - a. Recirculating systems which may expose persons in other occupiable areas;
 - b. Residual activity present during scheduled maintenance work;
 - c. Shielding needs around circulating pumps, heat exchangers, and holding tanks;
 - d. Discharge into the sewer (Also see radioactive waste handling in Section XIII); and
 - e. Periodic analysis of cooling media to detect contamination and/or build-up of induced activity.
8. Airborne radioactive material. Discuss procedures for the following hazards:
 - a. Production of radioactive gases by the accelerator beam passing through air (depending on energy and intensity);
 - b. Radioactive gases produced internally in the targets that might escape into the target areas, or into the accelerator vault or other areas as a result of a target containment system failure;
 - c. Contamination by particulates or dust, rupture of a powder target or flaking of activated surface layers of solid target material and leakage of activity past the target containment system barriers into the accelerator vault or other area; and
 - d. For commercial production, each of the items above should be addressed for each product produced.

Note: Shielding criteria and evaluation should be discussed further in Part XII of this guide.

D. Maintenance and Inspection.

Provide schedules for maintenance and inspection of all radiological safety systems, discussing the following:

1. What will be done for each system and how often the operations are to be performed.
2. The individuals who will perform each task with respect to assignment of responsibilities and the minimum training and experience to be required to perform the task.
3. The records to be kept and who will review them for timeliness, completeness and further work or investigation, as the need is indicated.

The above should address the more complicated routine tests and maintenance items, beyond surveys and observations of gauge readings. It should include such items as pressure tests of containment systems, mechanical or radiological re-evaluation of shielding, verifying potency of fluid handling systems (cooling, ventilation, exhaust) and comprehensive evaluation, maintenance and repair of mechanical systems needed for safety.

III. General Non-Radiological Safety Rules

- A. Provide a copy of the general safety rules for users and maintenance personnel in addition to the requirement of Section II.C. These should include:
 1. Use and maintenance of high voltage, high power electrical and radio frequency energy equipment;
 2. Storage and safe use of chemicals;
 3. Storage and safe use of gases;
 4. Safety supplies;
 5. Machine shop conditions;
 6. Elimination of and control mechanisms for fire and mechanical hazards;
 7. Emergency lighting and power;
 8. Maintenance and use of special safety equipment, such as ventilation systems, respirators, safety glasses, self-contained breathing apparatus and air sampling equipment; and
 9. Handling procedures involving toxic materials.
- B. Also discuss specific procedures for non-radiological safety. These should include:
 1. Fire and explosion of experimental equipment;
 2. Containing potentially flammable materials and keeping sources of ignition to a minimum;

3. Examining tubing and connections in systems handling dangerous materials;
4. Providing dedicated exhaust systems for gases (other than for containment of radiogases or particulates);
5. Testing and drills for emergency systems;
6. Defining hazardous areas;
7. Proper postings for all hazards;
8. Mechanical safety for set-up of experiment (railings, ladders, catwalks, platforms). This should also include initial and periodic load testing, in accordance with accepted engineering practice, of all lifting devices and systems used to handle loads in excess of 100 pounds; and
9. Vacuum Safety to include mechanical integrity against implosion and diffusion pump thermal safeguards.

Describe interactions (and prioritizing) of general safety rules and procedures with those for radiation safety, when they occur. For example, discuss how will general safety inspections or operations will be accomplished in radiation restricted areas, or how radioactive flammables will be safety stored.

Note: One safety manual may be developed to cover all safety topics. Sections should be labeled and a table of contents provided. Pages should be serially numbered.

IV. Radiation Monitoring Instrumentation and Leak Tests

A. Monitoring Instrumentation

List the make and model number of survey instruments. Identify the type of radiation to be detected by each, the energy and dose rate dependence and the sensitivity ranges of each instrument (see Appendix C also). Describe high and low range radiation instrumentation for monitoring beam exit ports and exhaust vents. Show where all instruments will be stored or made available.

- B. Describe procedures for calibration of room area radiation monitors, portal monitors and survey instruments.
- C. Describe procedures for performing leak tests.
- D. Describe how stack monitors are calibrated or made quantitative.
- E. If not described for Item 13.B., discuss visual/aural/monitoring systems used to maintain surveillance in the vault from each location where activities in the vault can be normally controlled (accelerator controls, remote targetry controls). Discuss recording systems for these monitors which would facilitate accident investigations, teaching operations and performance review.

V. Survey Program

- A. Drawings showing radiation hazards. Indicate on a scale layout, for typical uses, the

projected or measured:

1. Exposure rates in all occupied areas when the beam is on, and for each type of production where there will be significant differences.
2. Determine skyshine, where appropriate.
3. Measurement of residual radioactivity in the accelerator vault and any other equipment room when the beam is off.
4. Residual activity in targets and their locations.

This information should be much more comprehensive than that indicated in the facility design section, Item 13.B.10. or 13.C. , and should be provided specifically.

- B. Drawings showing administrative determinations. Indicate on floor plans the following areas based on projections or actual survey results:
1. Restricted areas;
 2. Unrestricted areas;
 3. Areas where limited occupancy may be permitted for operational reasons (personnel monitoring required);
 4. Areas where supplementary shielding is needed in order to permit unrestricted occupancy; and
 5. High radiation areas and access controls for these areas.
- C. Define a formal survey and review program for determining:
1. Unintentional or uncontrolled creation of radiation (radiation due to misalignment);
 2. Back-streaming (in potential drop accelerators) where the beam of charged particles accelerated from the ion source to the target causes a stream of particles of opposite charge to be released and accelerated in the opposite direction;
 3. Ventilation ducts and shield wall penetrations for other ducts or conduits, and hatches or other shield openings. Also describe how these can be locked to prevent their being opened inadvertently, during beam operation;
 4. Beam stop surveys (appearance and/or mechanical indications should also be checked);
 5. Skyshine for neutrons in energy range from 1 to 10 MeV and scattered photon radiation. (Note: It should not be assumed that if radiation dose rates are within limits close to the shield of the accelerator, they are always lower further away);
 6. Representative wipes of the floor where contaminated dusts or other

contamination may be found;

7. Special situations which may exist or be created after each major beam current or energy change; and
 8. Monitoring room air concentration when beam is on, and off, and prior to allowing entry to maintain or change a target or perform an adjustment. Give sample calculations for air activation by accelerator beams passing through air, if any exposed, or open beam, conditions will exist.
- D. Survey results/records for planning purposes. This section is considered critical for accelerator facilities. Indicate how you will define:
1. Working times and authorizations required for urgent repairs (over-time, long-lived activities may build up which are not appreciably affected by short delays).
 2. Schedules, for maintenance or repairs, to minimize exposures.
 3. Area restrictions based on studies of activation. You should address annual studies made to determine the levels of radiation intensity and to plot activation decay curves for several locations around the accelerator, and for each other location, where frequent routine maintenance or adjustment is required.
 4. A prospective dose limitation system which prescribes maximum daily and quarterly doses which are allowable for routine operations. Show what will be done when these prospective limits are exceeded. Describe how operations will be accomplished when all trained accelerator facility individuals have exceeded their prospective dose limits. Indicate what pre-planning must occur for operations outside normal production and routine (repetitive) maintenance, where exposures are likely to be significant.
- E. Contamination surveys (see also Appendix C)

Discuss details of methods for performing surveys, including:

1. Methods of counting wipe tests, including make/model of counting equipment, standard sources used, and the calculation of efficiencies.
2. Action levels for removable contamination.
3. Frequencies for routine wipe tests, areas to be wiped, records to be kept.
4. Wipe tests for special procedures or when airborne particles are possible or expected. For example, wipe tests should be made when grinding or surface abrasion operations are conducted, whenever targets or highly activated components (e.g., greater than 50 mR per hour at one foot) are removed or replaced, or whenever the vacuum is broken or opened near such a device or target.
5. Wipe tests for commercial product distribution, including wipes of preparation equipment, in-house transport equipment, and final containers, for each product and production system.

VI. Personnel Monitoring

Define the program for personnel monitoring for users, technical and maintenance personnel. Note that persons performing maintenance must wear pocket dosimeters along with appropriate (accredited) regular monitoring devices. Describe:

- A. Radiation to be monitored and ranges for the dosimeters. Show that at least one dosimetry system is accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) for the radiation and ranges described.
- B. How accumulated doses will be recorded.
- C. A program for review of personnel monitoring records and use of the devices.
- D. A program for maintenance and assignment of pocket dosimeters, including procedures for use and evaluation of the devices, and action levels and corresponding actions for pocket dosimeters.

Licensees are strongly encouraged to also provide an indirect reading pocket dosimeter program (pocket chambers), under total control of the Assistant RSO for accelerator operations. These chambers should be initialized, assigned, collected, read and recorded by the Assistant RSO or other safety staff representative for each individual who enters the accelerator restricted area. In this manner, safety staff can assure that daily doses are adequately monitored and controlled by a system not prone to reading errors/tampering, or dependent on voluntary compliance.

- E. Individuals to be monitored and types of dosimeters to be used.
- F. Routine bioassays to assess ingestion, inhalation or absorption of radioactive materials. Detail methods used, action levels and corresponding corrective actions. Show how equipment is standardized and how activities of significance are detectable with these methods, (if the measurements and analyses are to be performed in-house).

Bioassays should be discussed where volatiles are handled in curie quantities inside containment systems or where non-volatile materials are handled in curie quantities, and for appreciable periods, outside containment systems. (Commercial production quantities need always to be handled inside containment systems, however.)

- G. Analysis of data on a time basis to spot trends, estimate routine exposures and make prospective dose allowances. Recommended is maintenance of a 52-week running total for each individual and graphical analysis of trends.

VII. Safety for Special Handling Procedures

Describe the program for radiation safety for the following, as applicable to your operations:

- A. Machining, grinding. Describe the controlled environment procedures and equipment to be used for removing radioactive metal by filing, drilling, grinding and sanding. Describe how the process will be closely monitored. Indicate how temporary or permanent tents, cabinets or hoods will be used to confine the particles. Describe ventilation to prevent inhalation, ingestion or spread of contamination throughout the building.

Include use of protective clothing, and special handling of specific tools. Describe containment of contaminated materials. Also see Section XIV on radioactive waste handling.

Note: All surface work or repairs on contaminated or activated components must be conducted in hoods, tents or other contamination control devices.

B. Vacuum system

1. Describe systems for vacuum pump exhaust streams to handle toxic or radioactive gases which result from leakage of targets or target failure. This is in addition to normal operations, described under Item 13.B.6.
2. Describe vacuum pump maintenance. Address vacuum system, pumps, pump oil, and contamination from over-heated, damaged, vaporized or burst targets.

C. Tritium - Describe special handling and safety procedures for this nuclide, including:

1. Any produced during bombardment by, or of, deuterium, with tritium gas being released, from the target or other device.
2. Out-gassing which contaminates beam tube assemblies, vacuum systems and exhausts.
3. Present as a material adsorbed or absorbed in a tritium target.
4. Leakage of tritium targets, inside and outside the vacuum system.
5. Build-up in electronic vacuum pumps. (Note: potentially high amounts of tritium may be present on the inner surfaces of the pumps.)
6. Tritium in various mechanical and diffusion vacuum pumps and trapped in oil.
7. Components of the accelerator system.
8. Material from pump exhausts which may be released to the environment.
9. Tritium in used oil and targets (particularly that contained in material through which it will not diffuse readily).
10. Storage of Tritium or Tritium targets, with controls for temperature, ventilation and releases (monitoring).

D. Targets for research and commercial products - Discuss utilization of (procedures for) targets, target systems (as opposed to general operating principles and illustrations requested in Item 13).

1. Describe targets by radioisotope, activity and design.
2. Indicate gas supplies, transmission methods or chemical processing systems, as appropriate.

3. Describe cooling mechanisms, furnaces, and associated exhausts as applicable.
4. Describe utilization of target containment systems, including details of the contamination control steps to be followed for target installation, adjustment, verification and removal. Double bag procedures should be described in detail, and illustration provided, if not submitted in Item 13.B. Describe handling procedures for targets having activity before irradiation and for targets after irradiation. Address target removal, storage in shielded areas, special handling tools and disposal.
5. Describe specific procedures for shielding, tool and area use for proper handling and storage of the radioactive parts, particularly the dees, deflectors, and target supports. Also discuss contamination control.

Note: These descriptions should include, or be contained in, a description of the steps to be followed for radioisotope production and their associated safe handling procedures. Separate descriptions should be provided for each commercial product. (See also F below)

E. Production and Distribution of Radiopharmaceuticals and Radiochemicals. Discuss details of the commercial and in-house processes for:

1. Target preparation and fabrication
 - a. Evaluation of fabricated targets and their impurities; and
 - b. Handling and storage.
2. Analysis of Yield
 - a. Determination of radioisotope and activity; and
 - b. Chemical separation.
3. Packaging, labeling, prescriptions.
4. Transportation of products (methods and routes).
5. Access restrictions unique to any product because of high fields or risk of contamination.
6. Storage procedures for feedstock, decay of intermediate products, or waste.
7. Waste disposition.
8. Radiopharmaceuticals. Provide process, feedstock and product quality control steps, specific to each radiopharmaceutical produced, include the following:
 - a. Quality control (radionuclidic purity) testing;
 - b. Radioactive impurities expected and their limits;

- c. Calibration time and storage/handling instructions and limitations;
 - d. Chemical separation and radiochemical purity;
 - e. U.S. Food and Drug Administration (FDA) Pharmaceutical Good Manufacturing Practices and New Drug Applications;
 - f. Breakthrough testing for generator type devices and criteria to be met for each device;
 - g. Sterility and pyrogenicity; and
 - h. Product labeling, packaging and delivery methods.
- 9. Surveys specific to the manufacturing steps for each pharmaceutical.
- 10. Spill procedures for each pharmaceutical, specific to the manufacturing methods.
- 11. Order handling procedures for products, including verification of authority to order (particularly for radiopharmaceuticals), to possess the products, and documentation of orders and associated verifications.
- F. Transportation of Radioactive Materials. For each transported product:
 - 1. Describe the use of transport systems (lifting and moving equipment, packages, labeling, etc.) for in house transport; and
 - 2. Show compliance with appropriate Department of Transportation (DOT) rules for shipments outside the facility which use public thoroughfares.
- G. Source Fabrication - Detail the following:
 - 1. Receipt of material;
 - 2. Chemical or physical preparations;
 - 3. Source construction;
 - 4. Final assembly of processing;
 - 5. Quality assurance testing;
 - 6. Leak testing;
 - 7. American Natural Standards Institute (ANSI) testing procedures; Sealed Source and Device Registry or Radioactive Material Reference manual evaluation;
 - 8. Transportation containers; and
 - 9. Shipping procedures.

VIII. Ventilation

Describe exhaust and ventilation safety procedures. Provide descriptions for how ventilation systems are to be used to assure safety in the facility, including:

- A. Operable systems: Identify what systems must be operating and what systems must be operable and available as backup systems, for each of the areas of use and for each type of use specific to each area.
- B. Controls: Identify how controls should be adjusted to produce adequate performance for each area in terms of flow rates and directions. Maintenance of acceptable pressure gradients from room to room should also be discussed.
- C. Describe performance parameters (Item 13.D.) to be met for the ventilation system and how these are documented and made available to the operators of the equipment.
- D. Discuss how personnel are to augment normal ventilation for special scheduled procedures or accidental spills.
- E. Provide procedures for isolation of specific areas for routine production, if needed, or for control of spills or contamination that may become airborne.
- F. Show design basis for releases from the facility by exhaust systems, including reasonable source term postulates, and discussion of trapping, holdup, and filtration methods.
- G. Indicate how exposures and ingestion limits are met in unrestricted areas outside your facility for stack releases, showing all assumptions and calculations. National Council on Radiation Protection and Measurements (NCRP) Report No. 123 methods should be followed.
- H. Indicate how ventilation system design will adequately handle releases from vacuum systems within the facility, including vacuum lines of any central system, and individual vacuum pumps within the facility.

Describe a comprehensive maintenance program for the ventilation system including detailed performance checks of components (fans, ducts and filters) and routine non-radiological monitoring of flow rates, pressure differentials, and operating and control systems for primary and backup circuits. Include description of leak testing.

IX. Radiological Air Monitoring

Show how the designs and results of safety and operating procedures (Item 13 and Section VIII) are verified by radiological monitoring.

- A. Describe monitoring systems for:
 - 1. Target rooms;
 - 2. Accelerator rooms;
 - 3. Occupiable areas;

4. Vacuum pump exhausts;
 5. Exhausts to the environment;
 6. Temporary or permanent enclosures (tents, cabinets, hoods) for maintenance operations that may generate airborne contamination; and
 7. Breathing zone monitoring for unusual operations that pose significant risks to personnel, or where breathing protection is to be used. (However, routine use of respirators for any operation, in lieu of containment systems, normally will not be considered).
- B. Describe instrumentation, filters, standard sources, and efficiencies of the counting and analysis equipment to be used for these surveys, and show that these systems (particularly the stack monitor) have sufficient sensitivity, range and recording capability to:
1. Detect continuous releases that would result in exposures of ten percent of the annual limits in unrestricted areas;
 2. Accurately measure bolus releases of maximum credible activity; and
 3. Integrate bolus releases to determine the total activity released, in accident situations.
- C. Show calculations to demonstrate compliance, by design, for airborne concentrations of radioactive material in restricted and unrestricted areas of your facility. Postulate reasonable source terms and explain your analysis and results here, if not addressed in Item 13.D. or Sections VIII.F. or VIII.G.
- D. Discuss a schedule for radiological air monitoring, including the nuclides, methods, equipment, goals (or action levels), and the frequency of sampling in each area.
- E. Indicate methods of record keeping.
- F. Filtration system and radiological monitoring - for systems with air filters provide the following:
1. Detailed drawings of the filter housings to illustrate radiological monitoring procedures;
 2. Descriptions of the type of filters;
 3. Procedures for the inspection of filters, including action levels and corrective actions;
 4. Schedules for inspection of filters; and
 5. Methods for replacement of filters with presumed or determined contamination.
- X. Procedures for Storage of Radioactive Material

- A. Discuss scheduling and/or schedules for available storage space and shielding for storage for decay of targets or other products which must be left to “cool” radiologically after bombardment, either to permit easier handling or to reduce impurities. Discuss the impact of these schedules on the storage of other material (accelerator components, etc.) which must occasionally be stored for decay.
- B. Describe procedures for using shielded storage areas, and shielding containers, for bombarded targets and other radioactive items.
- C. Indicate labeling, posting and access restriction rules.
- D. Address radioactive waste storage comprehensively and discuss interactions and conflicts with the other storage discussed above.

Describe monitoring and surveillance procedures for each of the above, to assure adequacy of procedures and their effective implementation.

XI. Training and Experience of Users, Technicians and Maintenance Personnel

- A. For individuals to be named on the license to work independently (without physical supervision) of others, describe their job duties and provide résumés, and describe minimum training and experience requirements for such staff positions. The résumés should detail their training and experience with accelerators and handling radioactive material (such as in a cyclotron facility producing and using positron-emitting isotopes) commensurate with their job duties and with the facilities established minimum requirements. At minimum, they should meet:

- 1. Training for radioactive materials users

Individuals to be authorized to handle uncontained radioactive material should have at least 200 hours of didactic training in basic radioisotope and positron emitting isotope handling techniques and at least 500 hours of supervised laboratory experience with uncontained radioactive material in a situation germane to the licensee’s situation.

- 2. Training for accelerator operators

- a. General Training

Individuals to be authorized to operate or to supervise the operation of the accelerator should have résumés which indicate extensive familiarity with medium energy (10-100 MeV) accelerator operations in general, and a strong background in engineering and/or the physical sciences. It is usually not feasible for the licensee to undertake this type of general training. The staffing policy should establish substantial minimums for both general training and experience, and for advanced training and experience in accelerator operations. These criteria will need to be submitted with the procedures, for Department concurrence.

- b. Specific Training

Individuals who are to operate or supervise the operation of the accelerator will also need substantial training and experience with the particular make and model of unit before they can be named on the license. Discuss specific training experiences in terms of subjects covered, classroom hours of didactic training, and the duration of supervised training and experience, in a program of similar scope, with an equivalent accelerator. This should include 200 hours of training in accelerator physics and radiation safety, targetry, radiochemistry, use of automated and semi-automated chemical synthesis devices, quality control, airborne emissions verification and evaluation and regulatory standards. Training should also include hands-on experience with relevant equipment and chemistry at a similar facility. Indicate where and when the training occurred and was successfully completed as well as the qualifications of the supervising individuals involved. If this is to be provided at your facility, discuss details of the training program and staff time and personnel to be made available. (Such training will normally be allowed only when sufficient personnel resources and time are available at your facility, so as not to compromise day to day operations with the training workload.)

- B. For individuals not to be named on the license, but rather to work in the presence of authorized users (usually certain operational and maintenance staff positions), describe their job duties and define acceptable safety education and training commensurate with those duties. This should include at a minimum:
1. All aspects of radiation safety related to their use of radioactive materials and accelerators, and, consideration of mechanical, electrical, toxic chemical fire and explosion hazards, as they pertain to your facility.
 2. Radiological hazards specific to your accelerator and radioactive material production facility.
 3. Applicable chapters of the North Dakota Radiological Health Rules.
 4. For any training to be given at your facility for these users, indicate the scope of training to be provided and submit a course syllabus with the hours of training for each subject or section indicated. Also discuss the training and qualifications of the instructors and explain how participation and successful completion of the training is documented. (Supply tests given and certificates, or equivalent.)

XII. Emergency Procedures

Provide a description of your radiological emergency procedures. These should include copies of specific methods for all types of emergencies and copies of summary procedures which will be posted in each room. Discuss:

- A. Methods for calculating safe reentry times;
- B. Protocol for conducting area surveys and contamination Surveys to assure compliance with the North Dakota Radiological Health Rules;
- C. Frequencies of practice emergency drills and content of drills;

- D. Handling of spills and contaminated items;
- E. Notification of personnel in the area, of local responsible individuals, on and off normal hours, and a summary of the requirements for Department notification; and
- F. Periodic in-service on past problems and incidents at other facilities with similar operations.

XIII. Shielding

- A. Describe the shielding calculations and initial analysis for design of shielding for the accelerator vault and auxiliary areas and structures needed for radiation safety. The shielding calculations and analysis should be performed by a qualified individual. Submit information on the qualifications of the individual performing the calculations and analysis.
 - 1. Submit vault shield drawings, shielding performance specifications and shielding calculations and measurements (mechanical/radiological, as available).
 - 2. Provide auxiliary laboratory shielding design descriptions and shield drawings, including shielded hot cells, glove boxes and fume hoods.
 - 3. Indicate shielding design provided for containers (storage, use, transport) including how the Department of Transportation (DOT) requirements are satisfied by such shielding.
- B. In addition to initial design analysis for routine operations, describe precautions for special situations. These should include:
 - 1. Auxiliary shielding for special configurations of the accelerator, its beam, auxiliary devices and magnets, and targets;
 - 2. Low energy electrons scattering around corners;
 - 3. Radiation escaping through ventilation ducts and other (perhaps unused) conduits as designs or uses change (major changes require license amendment);
 - 4. Leaks due to spacing around doors and weather-stripping;
 - 5. Cracks or openings other than duct penetrations in existing shielding;
 - 6. Modifications to the accelerator to produce higher beam energies, or intensities, or to accelerate different particles; and
 - 7. Deterioration of shielding material or structures.

XIV. Interlocks and Posting

- A. Interlocks - Describe how radiation warnings and interlocks are to be used. In particular, address how the system will be used to protect personnel (especially where an

accelerator is used by several research groups). Discuss examples such as the potential interaction of commercial production groups with in-house radiopharmaceutical users, one of which may be using the machine while the other requires access to restricted areas to work with their equipment.

Describe procedures for the use of fail-safe systems for:

1. Key switch on-off system;
 2. Console automatic shut off when door opens;
 3. Prevention of starting accelerator from anywhere other than the console;
 4. Disabling (scram) switches in target areas and experiment rooms;
 5. Console circuits, warning lights and sound alarms;
 6. Procedures for mandated inspection of hazardous areas (to evict personnel) before startup;
 7. Room monitors; and
 8. Warning and status lights in the accelerator vault, irradiation rooms, corridors, and at the control console.
- B. Signs - Indicate how the facility is marked to:
1. Identify where hazardous radiation levels could exist or do exist;
 2. Designate established occupancy times; and
 3. Restrict areas by physical means (movable or permanent barriers).
- C. Describe a program for review, and for inspection of the use and status, of the interlocks and of safety and warning signs and equipment, on a quarterly basis.

Note: This outline can also be used to supply the information needed for Facility Design, on interlocks, but the information described by this section is to be provided in the radiation safety manual as instruction and procedures for use of these systems.

XV. Decontamination

- A. Provide a separate procedures section, in addition to specific mention in other sections, for methods to be used for decontamination of equipment, materials and facilities.
- B. Discuss contamination action levels (fixed and removable) for release of equipment, materials and facilities for unrestricted use.
- C. Describe access restriction for those items or areas that cannot be decontaminated sufficiently for unrestricted use. Also discuss procedures for containment of such items or facilities and procedures for ultimate disposal or release.

XVI. Radioactive Waste

Provide comprehensive procedures which include at least the following items and their record keeping requirements.

- A. Describe methods of compliance with the North Dakota Radiological Health Rules for disposal of specific items, such as:
 - 1. Protective clothing;
 - 2. Contaminated tools and equipment;
 - 3. Cooling media;
 - 4. Targets and associated materials;
 - 5. Grindings and filings or other contaminated maintenance waste; and
 - 6. Radioactive gases.
- B. Releases to environment - describe procedures to assure that limits of Section VIII.F. are met for airborne releases (unless provided earlier) and procedures and calculations to assure that releases to the sewer demonstrate compliance with Department limits.
- C. Procedures for decay of waste in storage, including monitoring and record keeping.
- D. Describe release limits for solid waste and procedures for assuring that these limits are met.
- E. Recycled materials procedures and action levels to permit continued recycling.

Note: The North Dakota Radiological Health Rules require special waste licenses for receiving radioactive waste from others. A problem can occur when feedstock and irradiated materials are returned or transferred to licensees who also serve as suppliers of the feedstock. Explain carefully how such material which is transferred to other licensees is not transferred solely as waste to be disposed of by the recipient.
- F. Discuss how "mixed wastes" (waste material that is designated as both hazardous under the U.S. Environmental Protection Agency's Resource Conservation and Recovery Act guidelines and radioactive) are avoided or prevented. No near-term disposal options exist for mixed waste). Describe methods for preventing such wastes from being generated and for keeping hazardous wastes separate from radioactive wastes.
- G. Discuss the eventual decommissioning of the accelerator and how neutron-activated materials will be handled and disposed.

NOTES

Appendix B

Table 1. Radiation of Possible Concern in Occupiable Areas of Particle Accelerator Facilities

Accelerator	Particles Accelerated	Beam Energy MeV	Purpose of Operation	Radiation of Possible Concern in Occupiable Areas
Potential-drop	Protons Deuterons Alpha Particles	1-10 1-10 2-20	Research Neutron Production Neutron Radiography Activation Analysis	Fast Neutrons Thermal Neutrons Gamma Rays
	Electrons	1-10	Processing Radiography Therapy	Electrons X-rays
Electron Linear	Electrons	1-10	Processing Radiography Therapy	Electrons X-rays
	Electrons	>10	Research Neutron Production Neutron Radiography Activation Analysis	Electrons X-rays Fast Neutrons Thermal Neutrons Gamma Rays
Cyclotron	Protons Deuterons Alpha Particles	15-50 7.5-24 15-50	Research Isotope Production Neutron Production Neutron Radiography Activation Analysis	Fast Neutrons Thermal Neutrons Gamma Rays
Betatron	Electrons	1-50	Radiography Therapy	Electrons X-rays

NOTES

Appendix C

Methods and Frequency for Conducting Radiation Surveys

I. Introduction

When radioactive material is produced by an accelerator, activation of air, cooling fluids, targets and machine components, and contamination by activated gases, liquids, and particulates can create radiation hazards. Both radiation surveys and contamination surveys should be performed to prevent unnecessary radiation exposure to personnel, to define restricted areas, to determine safe reentry times for some of these areas, and to prevent the spread of contamination throughout the facility. Radiation field surveys are performed using a radiation survey instrument to assess the intensity of radiation fields from stored sources or fixed contamination, and removable contamination surveys are performed by taking wipe samples from surfaces and objects likely to be contaminated within the facility. Visual monitoring and surveillance should be employed to assure necessary restrictions are met. Monitoring of air/other media to determine concentrations of radioactive material present is not addressed here.

II. Methods of Surveys

Suggested methods for performing the two types of surveys are given below. Records of these surveys should be maintained for inspection by the Department and for the licensee's reference to document adequate safety procedure performance and to determine whether the radiation levels or the contamination levels remain constant or increase over a period of time.

- A. Radiation Level Surveys - A survey instrument capable of measuring levels as low as 0.1 mR/hr and as high as 2 R/hr should be used and the results recorded on a standard form showing location, date, person performing survey, instrument used, exposure levels, and corrective action taken, if any. A sketch of the area should be used to make an easily prepared and easily understood survey record. Where areas are encountered or expected that have fields exceeding 2 R per hour, a meter of higher range should be available and used.
- B. Contamination Level Surveys - A series of wipes using filter papers or swatches of cloth should be taken from those surfaces where contamination could exist. Areas where solutions are prepared, uncontained solids are handled, incoming packages are received, pipetting is performed, etc., are areas that may be contaminated. The wipes should be numbered or labeled and their location indicated on the sketch record as previously described. Each wipe should be rubbed over a surface area of about 100 square centimeters to maintain a consistent means of determining the amount of removable contamination. The wipes may be counted using a scintillation well counter, a proportional counter, or any other detector capable of detecting the small amount of contamination on the sample which would exceed the predetermined acceptable limits (see IV below).

III. Frequency of Surveys

The frequency of surveys depends upon the amount and type of radioactive material used and the circumstances of use. Listed below are examples which may be useful in determining how often to perform surveys. The greater the work load, the more often the surveys should be performed. Where accelerator schedule constraints do not allow adequate time for decay of induced activity to occur, surveys must be performed

frequently and before entry into production areas or removal of objects from the accelerator vault.

- A. Low Level Areas - Not less than once a month - Areas where in vitro tests on small samples are performed, samples are analyzed, (samples usually less than 100 microcuries each) , areas where radioactive materials or low level radioactive wastes are stored, unrestricted access is allowed, etc.
- B. Medium Level Areas - Not less than once a week - Areas adjacent to the accelerator room, areas where millicurie amounts of contained radioactive material are handled or areas where contained activated components or radioactive waste in the millicurie range are stored.
- C. High Level Areas - Not less than once a day - Areas used for storage of active solutions, preparation, production and packaging of radioactive materials; fume hoods, glove boxes; emergency situations to determine safe reentry times, special procedures; any area where uncontained material in excess of 100 millicuries is handled or radioactive waste or activated components, in several hundred millicuries, are stored.

IV. Acceptable Limits

- A. Radiation Levels - In no unrestricted (uncontrolled) area may radiation levels exist such that a person could receive 100 mR in any one year, 25 mR in any seven consecutive days, or 2.0 mR in any one hour. If such areas are found, measures need to be taken to eliminate the excessive radiation levels. Additional shielding or relocation of radioactive material may be required. For restricted areas, the applicant should establish and submit descriptions of acceptable radiation levels that are as low as reasonably achievable.
- B. Contamination Limits - If the wipe samples counted indicate more than 1,000 disintegrations per minute (dpm) beta/gamma or 100 dpm alpha, the area should be cleaned until the contamination has been removed. If the contamination is not removable, the area should be restricted; the contamination contained and shielded, and allowed to decay to acceptable levels. Limits need to be met for unrestricted areas. This will help prevent spreading of contamination/ingestion of activity by personnel.

V. Performance of Surveys

Accelerator facility operators and technicians should be assigned to perform surveys, and facility management staff should be assigned to supervise the performance of these surveys, to review the results, to determine and enforce restrictions based on those survey results, and to perform surveys themselves on an emergency basis. The personnel designated to routinely perform these surveying duties should have proper training and experience in the surveys required for accelerator facilities including mixed-field surveys, knowledge of limits, reporting, and notification requirements, and be aware of who to inform at the facility when problems are discovered. The accelerator facility Radiation Safety Officer and the institution's Radiological Safety Officer should provide consultation, oversight and review of the accelerator facility management's and staff's performance and should conduct independent surveys for audits of the program.

Appendix D

General Laboratory Rules

The following is an example of typical rules that could be specified for a laboratory in an accelerator facility using, producing or preparing radioactive material. The applicant is encouraged to develop their own set of rules specific to individual needs and reflective of the actual laboratory situation. Use of material which may become airborne (aerosols, gases, or volatiles) or activated (objects, structures) will necessitate additional rules, as will alpha emitters and the use of large activity sealed sources. Rules should be written in the form of directions to be followed by employees.

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive material is used.
2. Wear disposable gloves at all times while handling uncontained radioactive material (material not in the form of manufactured sealed sources). Wear shoe covers at all times when in restricted areas.
3. Monitor hands and clothing for contamination after each procedure or before leaving the area.
4. Always use remote handling devices and shielded containers with millicurie amounts of activity.
5. Do not eat, drink, smoke, or apply cosmetics in any area where uncontained radioactive material is stored or used.
6. Do not store food, drink, or personal effects where radioactive material is used or stored.
7. Wear personnel monitoring devices (i.e., film badge or TLD, and pocket dosimeters, as appropriate) at all times while in areas where radioactive material is used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices, when not being worn to monitor occupational exposures, should be stored in a designated low background area, as should the control badge.
8. Wear approved finger badges when handling millicurie amounts of radioactivity.
9. Dispose of radioactive waste only in specially-labeled and properly shielded receptacles.
10. Never pipette by mouth.
11. Survey areas where radioactive material is used in uncontained form after each procedure or at the end of the day. Decontaminate if necessary.
12. Confine radioactive solutions in covered containers which are plainly identified and labeled with name of the compound, radionuclide, date, activity, and radiation level, if applicable. Shield the containers as necessary.
13. Transport radioactive material in shielded containers when necessary, to protect against external radiation exposure.

14. Work over surfaces which are easily cleaned or covered with disposable, absorbent coverings when handling small quantities of open solutions of radioactive material. Work only in designated restricted-use areas and with the prescribed shielding and contamination control equipment. Process volatile radioactive materials in fume hoods. Use glove boxes, or equivalent containment, when processing radioactive material, such as alpha-emitting materials or accelerator targets, whose activity or type of emission presents a significant hazard.
15. Survey and wipe test all objects and materials before removal from the accelerator vault.
16. Perform area surveys before entering the accelerator vault, after the end of target bombardment.
17. Perform maintenance and repairs only after receiving clearance from the Radiation Safety officer.
18. Perform contamination surveys upon entry into accelerator vault, when uncontained radioactive material may be present.
19. Consult remote read-out area monitors, portable survey instruments, and air monitors before entering, and during entry of the accelerator vault, or other high radiation areas.

NOTES

Appendix E

Requests for authorizations for production of radioactive material with accelerators should be patterned after those listed below. Provision for materials in storage, for pharmaceutical precursors, and for commercially distributed materials and their co-produced and daughter products should be made as indicated. The quantities given in the third column should be nominal production values based upon proper machine operation at design specifications.

Operation outside normal parameters which would affect yields to the extent that requested possession limits would be exceeded (for co-produced or daughter nuclides) should be undertaken only subsequent to a specific license amendment authorizing such operation and which includes any changes needed in possession limits.

The last sample authorization is for miscellaneous trace materials expected to be produced by typical systems, but for which specific safety measures are not likely to be needed.

A. Activation products	A. Solid articles associated with the cyclotron, beam line or rooms of the facility	A. As activated by operation of the cyclotron	A. For use and storage in place, or storage on site, as incidental products of cyclotron operations. Not for production of radioactive materials.
B. C-11	B. Carbon monoxide and carbon dioxide, as gases	B. 2 Ci	B. For preparation, from bombarded targets, of radiochemicals and radiopharmaceuticals
C. Pb-201 and co-produced or daughter nuclides Tl-201, Pb-202m, Pb-204m, Tl-202	C. Solid (plated accelerator targets)	C. 30 Ci/15 Ci/ 3.2 Ci/1.7 Ci/ 0.48 Ci, respectively	C. Production of Tl-201; testing and distribution to authorized recipients
D. Ga-67 and co-produced nuclides Ga-68, Ga-66	D. Solid (plated accelerator targets)	D. 50 Ci/5 Ci/ 0.3 Ci, respectively	D. Production of Ga-67; testing and distribution to authorized recipients
E. In-111 and co-produced nuclides In-112m, In-112	E. Solid (plated accelerator targets)	E. 10 Ci/3 Ci/ 3 Ci, respectively	E. Production of In-111; testing and distribution to authorized recipients
F. Co-57 and co-produced nuclide Ni-57	F. Solid (plated accelerator targets)	F. 5 Ci/0.5 Ci respectively	F. Production of Co-57; testing and distribution to authorized recipients
G. W-178/Ta-178 and co-produced nuclides W-179, Ta-179	G. Solid (plated accelerator targets)	G. 5 Ci each/ 1 Ci/1 Ci, respectively	G. Production of W-178/Ta-178; testing and distribution to authorized recipients
H. Any radionuclide with Atomic Number less than 84 as a co-produced or a daughter nuclide from the production of Tl-201, Ga-67, In-111, Co-57 and W-178/Ta-178	H. Solid (plated accelerator targets)	H. 0.2 Ci	H. Production of radioactive material as otherwise authorized by this license

NOTES

Appendix F

Additional Safety Procedures

Additional procedures in use at a hot-cell equipped medical facility with a mission of radiopharmaceutical and commercial radiochemical production are mentioned below. While these procedures may be appropriate at an accelerator facility as experience, prudence and workload increases dictate, they are not being required with initial submissions.

1. For the facility as a whole, real-time air monitoring and chart recording of radioactive gas releases is provided. Calibration of associated instrumentation is by release of known quantities of radioactive gases at two concentrations. This allows quantitative assessment of accidental releases after the fact, as well as calibrated monitoring of routine releases.
2. Personnel monitoring, for those involved in processing activities, includes indirect reading dosimeters, whole body, wrist and finger badges, and digital/audible monitors or direct reading dosimeters. Pocket dosimeter readings are posted weekly.
3. Bioassays of personnel include whole body counting (baseline and quarterly) with action levels at 1/10 of the International Commission on Radiological Protection (ICRP) 30 Annual Limits on Intake (ALI's). Calibration is with a Medical Internal Radiation Dose Committee (MIRD) chest phantom. H-3 and Iodine bioassays as applicable.
4. Supplemental air sampling is conducted in breathing zones, with action levels at 1/10 of ICRP 30 Derived Air Concentrations (DAC's).
5. Shoe covers are worn in all processing areas; hands washed and hands, clothing and feet monitored each time processing area is exited.
6. All fixed instrumentation for radiation detection is provided with local as well as remote (control panel) readout.
7. Annunciator system is provided which integrates radiation, utilities and safety surveillance. Utilities surveillance includes water temperatures and pressures for the mains, chiller lines, cyclotron lines, target lines, and buffer lines. Waste sump level is also integrated. Safety systems surveillance includes all restricted area door positions and scram switches.
8. Operating mechanisms for doors to high radiation areas sound warnings before closure to alert individuals who may unknowingly be present in the high radiation area to the potential danger.
9. Safety glasses, gloves, head and shoe covers, all dosimeters and presence of two individuals is required for each entry into hot cells, irradiation rooms or the cyclotron vault, and is also required for maintenance on cyclotron peripheral equipment.
10. Automatic bypass air circulation is provided for rooms, which are individually isolated in case of accidents. This allows room by room shutdown of affected areas, without disruption (and loss of cooling and dilution/exhaust) to other areas, and a more graded response to emergency situations.

11. Written procedures for specific accident scenarios, including the following: target failure (rupture or vaporization) , spills or releases outside a containment enclosure, personnel contamination, personnel inhalation or ingestion, personnel exposures greater than 100 mrad, leaks between buffer water and main chiller water, malfunction of air supply or exhaust systems, and high levels in exhaust monitors or systems.

Some of these procedures can be adopted for an ALARA program as the cyclotron health physicist establishes technical specifications for the production operations. Others may require extensive design or fitting, and alternatives may need to be sought if their importance is elevated, by experience or expansion of production, to the point where they need to be required.

The procedures mentioned above are in addition to full hot-cell containment and remote manipulation of all accelerator products, for the cited facility.

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**REGULATORY CONSIDERATIONS FOR THE MONITORING OF EMISSIONS
FROM MEDICAL RADIONUCLIDE PRODUCING CYCLOTRONS**

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INTRODUCTION

Molecular imaging modalities have rapidly assumed a fundamental position in the diagnostic armamentarium of nuclear medicine. Among the various imaging modalities now available to generate an image of a biological structure or process, Positron Emission Tomography (PET) has recently assumed a position of primary importance. PET provides the ability to visualize an ever-expanding array of molecular processes in a manner that is noninvasive, of reasonable resolution, and relatively cost-effective. Positrons emitted from PET radionuclides produce 511 keV gammas through annihilation; the two photons released from each annihilation enable coincidence counting, and facilitate cross-sectional image reconstruction. PET is now routinely used in oncology to image tumors via glucose metabolism (in the United States) and is also utilized in the specialties of clinical neurology, cardiology and vascular disease.¹ It is also utilized for drug development and metabolic research.

Despite becoming available for clinical use in the mid-1980s, and despite the obvious utility of PET for a variety of scanning purposes, the technique has been slow to become widely utilized²; there are certainly a variety of reasons for this, ranging from reluctance on the part of care providers to invest the initial capital costs of facility startup, through lack of FDA approval for specific PET procedures, to uncertain insurance compensation. Through March 12, 2000, Medicare provided coverage for only six specific procedures,³ and private insurance providers, while not entirely unsupportive in this regard, have chosen to consider many PET procedures experimental, expensive, and uncompensable until such time as the FDA approved them for specific indications.

The FDA first approved a PET imaging agent in 1972 (which is no longer marketed). Although ⁸²Rb chloride was approved in 1989 to assess regional myocardial perfusion, and [¹⁸F] fluorodeoxyglucose (FDG) was approved the same year for the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures, no other agent was approved until March 12, 2000.⁴ On that date, "FDG was specifically approved for assessing abnormal glucose metabolism to assist in evaluating malignancy in patients with known or suspected abnormalities found by other testing modalities or in patients with an existing diagnosis of cancer." Additionally, "FDG was specifically approved for imaging of patients with coronary artery disease and left ventricular dysfunction, and when used together with myocardial perfusion imaging for identification of left ventricular myocardium with residual glucose metabolism and possible reversible loss of systolic function."⁵

In addition to the approval that has been given by the FDA for [¹⁸F]FDG use in identifying and characterizing malignancies and cardiac dysfunction, two huge areas of potential application, the Health Care Finance Administration is shortly expected to expand coverage for a variety of diagnostic procedures.⁶ Because of these factors the "floodgates have opened" and a rush to provide PET services has ensued. Before March 12, 2000, New York State had permitted four accelerators to produce positron emitters for clinical and research use; since that date, three additional facilities have opened or are under construction, and four more are known to be in the serious planning stage, with the assurance of more to come. While New York has a high doctor-to-patient ratio relative to many other States, and therefore might tend to attract medical facility investments in what is initially a disproportionate manner, this rapid siting of cyclotrons will almost certainly become a national phenomenon. This proliferation of medical

cyclotrons will become a major issue for the States, both Agreement States and otherwise, as our efforts to monitor emissions from these facilities have demonstrated that they are, as a class, the largest sources in our State of potential dose to the public via the atmospheric pathway for State-regulated facilities. Additionally, we have found that medical cyclotrons have considerable potential for violating the 10 mrem Constraint Rule of 10 CFR 20.1101 and equivalent State regulations. This paper details the authors' findings in regard to exercising technical and regulatory oversight of emissions to the air from positron-emitter-producing medical cyclotrons, and attempts to condense our experience into a form that will prove to be quickly and easily assimilable by those involved with permitting, discharge monitoring and dose assessments.

BRIEF OVERVIEW OF CYCLOTRON OPERATIONS AND POSITRON-EMITTING PRODUCTS FOR PET IMAGING

This section presents a brief and highly simplified overview of the features of cyclotrons relevant to the monitoring of emissions of positron emitters to the environment. Issues related to the production of radionuclides other than positron emitters, and those issues specifically related to cyclotron licensure, such as exposure, shielding, activation, etc., are beyond the scope of this presentation.

CYCLOTRON BASICS

The *cyclotron* is a device designed to accelerate charged particles. Ernest O. Lawrence conceived the concept of the cyclotron in 1929 at the University of California, and developed it as an instrument of research in the 1930s.

Cyclotrons accelerate particles in what is basically a very simple manner: a charged particle is shot into a uniform magnetic field generated between the faces of two large electromagnets. The magnetic field component generated by the magnets points in a direction perpendicular to the magnet faces; this means that the force on the moving particle between the magnets will always be pointed in a radial direction, perpendicular to the plane of motion. A force pointing perpendicularly to the direction of motion of a particle can only change the particle's direction, not the magnitude of its velocity. Particles are generally injected into the magnetic field near the center of the magnets; the outwardly directed radial force on the particles makes their trajectories spiral outward toward the periphery of the magnets.

Between the magnets are two hollow metal pole pieces, called "dees," that are separated by a vertical gap, across which flies the particle. To accelerate the particle, an electric field is generated across the gap. The electric field oscillates back and forth in direction at a frequency that just matches the transits of the particles, so that the particles are always being accelerated across the gap. Each transit occurs farther out toward the periphery; once the particles are near the edges of the magnets they are directed outwards toward the target. All of this takes place in a high vacuum, so that the accelerated particles have a mean free path of sufficient magnitude to give them a relatively clear shot at the target.

Cyclotrons are not useful for accelerating particles to very high energies; for this reason they are not used as primary instruments for research into atomic structure. They are quite useful, however, for accelerating protons and deuterons to modest energies, which is most useful for the purpose of creating low-atomic-number positron-emitting radionuclides. Many cyclotrons accelerate H^- ions rather than H^+ ions; in this case the negative ions are stripped of their electrons by passing them through a thin carbon foil before they hit the target. Beam energies and currents necessary for the production of PET nuclides vary widely, depending upon particle accelerated, design parameters and requirements; commonly encountered maximum beam energies for these cyclotrons will range from 7 to 40 MeV for protons, with beam currents anywhere from less than 30 μA to several milliamps.

CYCLOTRON AND RADIOPHARMACEUTICAL MANUFACTURERS AND SUPPLIERS

A number of manufacturers build cyclotrons specifically designed for the production of positron emitters for PET (and SPECT—Single Photon Emission Computerized Tomography) and market them internationally. Some of those likely to be encountered by the regulator are listed in Table 1.

Among the companies supplying positron-emitting radiopharmaceuticals for clinical diagnostic use in North America are P.E.T.Net Pharmaceutical Services, Syncor International, Eastern Isotopes and PharmaLogic P.E.T. Services, LLC.

Table 1. International manufacturers of cyclotrons designed to produce positron-emitting radiopharmaceuticals

Manufacturer	Current production models	Automated chemistry unit available
EBCO	TR30, TR19, TR19HC	Yes
CTI	RDS 111	Yes
IBA	18/9, 10/5, 3	Yes
GE	PETtrace	Yes

TRACER PRODUCTS AND USES

While ^{18}F is currently by far the most utilized positron-emitting radionuclide (PER), and [^{18}F]FDG constitutes the only PER product of most commercial radiopharmaceutical suppliers, several other PERs (^{11}C , ^{13}N and ^{15}O) are commonly utilized in clinical research. These PERs are routinely produced at cyclotrons located at medical centers that conduct clinical research, and potentially can be very significant contributors to dose to the public via the atmospheric pathway. Table 2 provides pertinent information about the decay of these nuclides.

Table 2. Decay data for positron-emitting radionuclides commonly utilized for PET studies⁷

Radionuclide	Half-life	Daughter	$E_{\beta+\text{max}}$ (MeV)	$E_{\beta+\text{avg}}$ (MeV)
^{11}C	20.48 min	^{11}B	.960100	.385600
^{13}N	9.97 min	^{13}C	1.198500	.491800
^{15}O	122.24 s	^{15}N	1.731900	.735200
^{18}F	109.74 min	^{18}O	.633500	.249800

Each nuclide may be created as a constituent atom of a variety of chemical compounds; the target material is chosen according to the desired end-product. Target materials are contained within containers called targets located in the beam line at a location called the beam extraction radius. Target materials are typically liquids or gases; the targets retain their contents while allowing activation through the use of high-strength low-cross-section target windows. A variety of materials are used for both targets and target windows; in all cases, target failure is possible, and this is one method by which loss of all or part of a reaction product may occur. In most cases, the product compound will need further chemical processing to produce the desired agent in a purified form for injection, ingestion or inhalation. Table 3 lists reactions commonly utilized to obtain the desired PER, and associated target production materials.

Tracers commonly utilized for clinical applications and research are listed below, along with information in regard to their application.⁸

Table 3. Reactions and common reaction products

Reaction	Common reaction products
$^{14}\text{N}(\text{p},\alpha)^{11}\text{C}$	$^{11}\text{CO}_2$, H^{11}CN , ^{11}CO , $^{11}\text{CH}_4$
$^{13}\text{C}(\text{p},\text{n})^{13}\text{N}$; $^{16}\text{O}(\text{p},\alpha)^{13}\text{N}$	$^{13}\text{NH}_3$, $^{13}\text{NO}_2$, $^{13}\text{NO}_3$, $^{13}\text{N}_4$
$^{15}\text{N}(\text{p},\text{n})^{15}\text{O}$; $^{14}\text{N}(\text{d},\text{n})^{15}\text{O}$	$^{15}\text{O}_2$, C^{15}O , C^{15}O_2 , H_2^{15}O
$^{18}\text{O}(\text{p},\text{n})^{18}\text{F}$	$^{18}\text{F}^-$, H^{18}F , F^{18}F

¹⁸F tracers

FDG. [¹⁸F]fluorodeoxyglucose is used as a marker of glucose metabolism. It is moved into cells by the glucose transporter and phosphorylated by hexokinase to FDG-6-phosphate. Because an oxygen atom has been replaced by fluorine at the second carbon position, FDG-6-phosphate cannot be metabolized by the glycolytic pathway, and remains in the cell for substantial periods of time. As such, it is useful for marking cells which have exceptional energy needs, such as the heart and brain, and for localizing and sizing tumors. Because aggressive tumors have exceptional energy needs, it can also be used to differentiate between benign and aggressive tumors.

Fluorodopa. L-DOPA is the precursor for the neurotransmitter dopamine. Radiolabeled L-DOPA attaches to dopamine receptors, and is used for clinical assessments of dopaminergic function and basic research into neurotransmission and associated disease states.

Fluoroethylspiperone. Radiolabeled fluoroethylspiperone is used for research into dopamine D2 receptors.

Fluorouracil. 5-Fluorouracil is an antineoplastic agent that interferes with the synthesis of both DNA and RNA. It is commonly used for therapy of a variety of cancers, such as breast, cervical and ovarian cancer, and topically for actinic keratoses. Its use as a tracer involves the study of the delivery of chemotherapeutic agents to tumors.

Fluorine ion. ¹⁸F⁻ can be used for clinical bone scanning.

¹³N tracers

Ammonia. Radiolabeled ammonia is widely used for myocardial blood perfusion studies in the evaluation of coronary artery disease. [¹³N]ammonia tissue concentrations are almost linearly proportional to flow over a fairly wide flow rate; this fact makes [¹³N]ammonia useful for determining the degree of stenosis in coronary vessels.

¹⁵O tracers

Water. [¹⁵O]labeled water is used for myocardial blood perfusion studies, in much the same manner as [¹³N]ammonia. It has a major disadvantage in that the large amounts of labeled water in the cardiac chambers, parts of the myocardium and the lungs obscures measurements of tracer concentrations the myocardium.

Oxygen. Labeled oxygen can be used to qualitate tissue necrosis.

CO₂. Labeled carbon dioxide can be used to study cerebral blood flow.

¹¹C tracers

Acetate. Used for measuring oxidative metabolism.

Deprenyl. Deprenyl is a monamine oxidase B (MAOB) inhibitor commonly used for treatment of parkinsonism; labeled deprenyl is an effective way of mapping MAOB receptors in the brain.

Leucine and methionine. These amino acids, when labeled, can be used as markers of protein synthesis, thus providing a measure of tumor viability.

N-Methylspiperone and raclopride. These compounds are among a number of compounds used to study dopamine receptors (in this case, D2 receptors).

AUTOMATED CHEMISTRY UNITS

PERs are generally produced as constituent atoms of simple compounds. These simple compounds often require a variety of chemical transformations in order to obtain the desired tracer compound. Because handling the significant activities produced is hazardous, automated synthesis units have been designed to perform many synthesis procedures automatically.

Automated chemistry modules are usually fairly compact self-contained units that sit in a hot cell; they are frequently fed radioproducts directly from the target chamber by dedicated liquid and gas supply lines, minimizing exposure to personnel. Most units are computer controlled, either via an internal microprocessor or by an external computer. Synthesis duration and yield are of course dependent upon the individual unit and the synthetic pathway. Units are usually designed only for a single type of synthesis. Each unit will leak its radionuclide products to a greater or lesser extent; among the variables affecting release are volatility of individual synthesis components, the design of the system, the number of steps involved, reaction chemistry, and whether or not filtration is utilized. It is not possible to know *a priori* just how leaky a given unit will be in use.

MONITORING OF EMISSIONS

Typically, emissions of PERs will be caused one of three factors.

1. *Target foil failure.* Breakage of the high-pressure foil on a target is not at all unusual during a synthesis, and may result in complete loss of product. The occurrence of foil rupture may be minimized by the routine replacement of targets.
2. *Transport system failure.* This may occur either through mechanical failure (leakage) or human error (accident). Mechanical transfer systems typically utilize Teflon tubing and valves that are coated with Teflon. Tubing and ferrule failure can occur, as can leakage around the ball of poorly seated ball valves.
3. *Releases during syntheses.* Many syntheses will result in one or more volatile compounds being synthesized. The extent of release of these compounds is entirely dependent upon the particular synthesis and the techniques used to perform them, either manual or automated.

Because of the observed potential for even small cyclotrons to produce emissions that could conceivably deliver annual doses to the public that exceed the 10 mrem constraint rule, the regulator needs to pay close attention to a wide variety of factors that can affect emissions and emission monitoring.

DETECTION POSSIBILITIES

Detectors utilized for the detection and quantitation of positron emitters in exhausts to the air function either by detecting the 511 keV annihilation gammas emitted from positron–electron annihilations, or by direct detection of positrons. Detectors typically feed their output into real-time radiological display, collection and tracking units that convert analog feed signals into activity and concentration data. These units now commonly consist of off-the-shelf computers running specialized application software. The software will generally provide a convenient display of real-time emission measurements, emitted activity over a specified time period, graphs for data and trend analysis, emission history and alarm status.

DETECTORS

A number of different detector types are utilized for monitoring the concentrations (and ultimately, total emitted activities) of PET radionuclides in exhaust streams. No one detector type has all desired qualities, and they are often used in pairs to compensate for deficiencies. As detector sensitivities and response characteristics will be found to vary by type, design, installation location, system geometry, positron energies, observed background levels and other factors, we will not present any recommended detector type or minimum sensitivity values. In our opinion the ultimate suitability of any particular detection

installation should be demonstrated by calibration *in-situ* with releases of appropriate activities of radionuclides.

Reactive materials may adsorb to the surfaces of duct materials and any detector that is located within a stack, and this adsorption can produce background readings that can be quite significant. Experience has shown that any material utilized in detector construction will adsorb ^{18}F and ^{18}FF very strongly; this includes stainless steel and Teflon. ^{13}N ammonia will also adsorb to metallic surfaces, and to galvanized duct in particular. Adsorption effects can be prominent, are compound-dependent, and are also dependent to some extent on system geometry and construction. These factors must be accounted for when determining system response, and are yet another reason to preclude use of factory derived response curves.

Ionization chambers

Non-pressurized ionization chambers (ICs) are a popular choice for this application. Advantages of these detectors are that they are relatively inexpensive and reliable, and are not likely to saturate under accident conditions. Disadvantages are that they can be affected by moisture, ions and aerosols, and their sensitivity can be quite marginal for characterization of low concentrations of PERs in rapidly moving (and therefore low-concentration) airstreams. Additionally, for externally mounted ICs fed by a sampling pump, if the exhaust velocity is too high in relation to pump draw, the chamber may miss counts of rapid releases.

ICs typically used to detect positrons will likely be flow-through detectors operating in current mode. We have observed both parallel-plate designs inserted directly into the exhaust stream, and cylindrical designs located externally from the stack and fed by a sampling pump. The true flow-through designs (i.e., those mounted in the exhaust duct) will be more responsive to the positron flux and resulting cascade than to annihilation gammas; the positron-to-gamma response ratio is a function of detector design and placement.

Scintillators

Nal(Tl). Thallium doped sodium iodide detectors are utilized because of relatively high sensitivity combined with low price. They are sensitive enough for low-concentration nuclide detection; it is possible, however, depending upon the system geometry and activities involved, to saturate these detectors under accident conditions, and for this reason their sole use as the only detector component of a monitoring system may not be advisable. Nal is, of course, hygroscopic and somewhat fragile, and is always utilized enclosed within a sealed chamber. Some systems locate the detector within the exhaust stack; in this configuration, the detector casing as well as the ductwork may adsorb exhaust products, which will contribute significantly to background. In any case, the detector casing and cabling must be especially well designed and truly weatherproof, or rapid deterioration will occur. Alternately, these detectors may be located exterior to the stack in a secure location, positioned to count a sample cartridge that is fed by a sampling pump. Nal has a rather long scintillation decay time, and this may impact unfavorably on detector performance in a high-background environment as can occur with exhaust system reactive-component adsorption.

BGO. Bismuth germanate ($\text{Bi}_4\text{Ge}_3\text{O}_{12}$, BGO) is relatively dense and of high effective atomic number; as such it is quite sensitive to a wide gamma energy range. The crystals are sturdy and nonhygroscopic. Their primary drawback for this use is one of cost, which is greater than that of comparable Nal detectors.

Plastic beta scintillators. While generally utilized for beta-minus detection, plastic scintillators can be used for direct positron detection as well; the specific energy loss and range of positrons in materials is roughly the same as for electrons. Given the overall low atomic number of plastic scintillators, they are relatively insensitive to gammas unless loaded with high-Z elements. Plastic scintillators are inexpensive, stable, and manufacturable in just about any conceivable shape. We know of only one manufacturer that utilizes this type of scintillator for PER detection in cyclotron exhausts.

Other detectors

Other types of detectors may be encountered for special purpose uses; some manufacturers offer Geiger-Mueller tubes, neutron dosimeters and other modalities as optional equipment.

FILTRATION AND DECAY TECHNOLOGIES

As noted above, not only are there many different target compounds which may serve as starting materials for nuclear particle interactions, but often these compounds undergo a variety of chemical transformations on their way to becoming the desired end product. Some of these compounds will be volatile, and will be released to varying extents during the process of manufacture. Of the products that are volatile and released to the exhaust system, some will be filterable, and some will not.

There are a number of methods for removing reaction products from the exhaust stream or otherwise minimizing activity releases; each has its own utility. Because of the magnitude of the potential dose to the public from cyclotron exhausts, it is essential for prospective cyclotron operators to consider the need for and applicability of discharge minimization measures before they begin construction of their facilities. Retrofitting is invariably expensive and always stressful to the relationship between customer and regulator. We strongly recommend that all prospective licensees/permittees be requested to submit their construction plans to your agency for review and consultation before their finalization.

Activated carbon filters

Activated carbon has an enormous surface-area-to-weight ratio; this huge surface area facilitates the adsorption of nonpolar molecules. Many emission products, especially reactive organic compounds, will be filterable to at least some extent with activated carbon. What will certainly not be filterable to any useful extent is anything normally present in air, such as O₂, N₂, H₂O and CO₂; the available adsorption sites will already be fairly saturated with these substances. In reality, there will be some exchange of molecules previously adsorbed for those present in the exhaust stream, and in effect some filtration will occur. In all cases, while efficiency estimates can be extremely useful, if the actual efficiencies for each filtrate are needed they will need to be determined at each facility by monitoring. The filtration efficiencies reported below have been observed at facilities with a single nuclear-grade carbon stack filter and reasonably representative configurations, and are reported for rough estimation use only; these values may or may not be representative of those encountered at other facilities.

The most commonly produced and exhausted PER is ¹⁸F; reaction products containing this nuclide have proven highly filterable by activated carbon. Net efficiencies observed at cyclotron facilities will vary with exhaust system design variables, such as amount of carbon, physical geometry of the filtration unit, exhaust flow rate, and age and integrity of the filter, but observed efficiencies have been at least 90%, with 95-97% or greater to be expected in a new system. We have generally observed somewhat lower filtration efficiencies for FDOPA, somewhere around 70%. While ¹¹CO₂ and ¹¹CO should be considered unfilterable with carbon, reactive organics containing ¹¹C should in general be quite filterable. CO₂ may be trapped with NaOH traps. ¹⁵O water vapor is unfilterable; ¹³N compounds vary with reactivity.

No matter how large the charge, carbon filters do not last forever, contrary to an often-stated opinion. We have seen more than a few very large filters (in terms of carbon weight) reach saturation, either with the expected filtrant or with paint fumes, water vapor, or contaminants unknown, rendering them useless. All filters must have an evaluation and replacement procedure as part of their committed maintenance routine.

Large-charge filters may last several years or more; smaller filters may be useless in a month or less. Because post-filtration monitoring will be in place at cyclotron facilities, it is reasonable for large and expensive filters to have a criterion in place by which filter degradation is identified, rather than relying upon routine filter replacement every so many months. If sufficient information is available to determine a theoretical filtrant capacity per gram of carbon, one may estimate a lifetime and institute an upper-bounds replacement period. Smaller filters, such as those located in automated chemistry units or in fume hoods, are more easily replaced periodically.

Reaction filters

Some commonly released products, such as $^{11}\text{CO}_2$ and $^{15}\text{O}_2$, are not filterable with activated carbon, but lend themselves to elimination from the exhaust stream through relatively simple and inexpensive chemical means. It may well be worth considering the utilization of what we refer to as a “reaction filter” at facilities where such a modality is practicable. Because carbon dioxide reacts with alkalis to yield carbonates or bicarbonates, simply passing $^{11}\text{CO}_2$ over NaOH pellets will result in the production of sodium bicarbonate, NaHCO_3 , and removal of much of the ^{11}C from the exhaust stream. The addition of a flow-through chamber containing NaOH to the exhaust system of an automated processing unit may in some instances be fairly trivial. We are aware of efforts to develop a simple procedure to remove $^{15}\text{O}_2$ from the processing exhaust stream.⁹

Particulate filters

Our experience with the results of particulate monitoring to date has indicated that particulate production is very minimal to unmeasurable from commonly performed PER syntheses; this is as expected, since routine syntheses are generally performed in closed and filtered reaction systems, and since particulates have not, to our knowledge, been observed as reaction products of these syntheses. In light of this observation, we have in the past not insisted on the installation of high-efficiency particulate arresting (HEPA) filters in exhaust systems from cyclotron producing only ^{18}F , where we are reasonably confident that significant particulate production is not taking place. However, given that there can always be changes made in reaction chemistry, and that the presence of pre-filters and HEPA filters extends the lifetimes of expensive carbon filters, we have started to recommend that both of these component be used at all installations. Routine and nonroutine change-out periods for these filters should be spelled out in the licensing process.

Containment and holdup

PERS have relatively short half-lives, on the order of minutes or hours. Increasing the time for decay before release thus constitutes a convenient and relatively easily implemented means by which the net activity of very short half-life nuclides released to the environment may be reduced. Obviously, the shorter the half-life of the nuclide to be released, the more effective any delaying mechanism will be; $^{15}\text{O}_2$, with a $T_{1/2}$ of 122.24 s, is the best candidate for this technique among commonly encountered nuclides.

The easiest way to delay release is simply to lengthen the exhaust path; transit time in a long duct is often considerable in relation to the half-life of a nuclide such as ^{15}O . As it is almost always best to locate emission points as far away from receptors as possible, and since this generally translates into having a release point as high as possible, this technique is often implemented automatically during facility planning.

However, some facility operators may fail to consider or implement ALARA (As Low As Reasonably Achievable) concepts in their facility design, and will need to be informed of the benefit of removing an emission point to the most remote location available. Facilities that produce ^{15}O will generally be large medical centers, which often have tall buildings nearby that may serve as convenient locations for an emission point.

We have been informed that waste gas decay tanks are utilized in European cyclotron facilities in order to facilitate significant decay of small-scale emissions before release to the air. We have not yet seen functioning gas decay installations in the United States, nor have we seen design documents for such installations; however, given what is presumably a treatment of simple design and moderate costs, their implementation probably should be considered by any facility planning to produce and emit large total activities. We have seen one facility that collected automated chemistry exhausts in a balloon for decay; we have no information about the specifics of this procedure, and presume that the practicality of this method is limited.

DETECTION SYSTEM CALIBRATION

In any arrangement of detectors used to quantify the concentrations of nuclides present in an exhaust stream, there will be a variety of factors that will affect instrument calibration. Some of these factors are familiar and expected, things such as instrument sensitivity, geometry, response characteristics, and so on.

These factors will normally (but not always) be accounted for in the calibration curves provided by the manufacturer for each of the detectors utilized. There will also be factors that are particular to individual

installations of these systems, that must be taken into account when evaluating system response to nuclide concentration; these factors are commonly ignored by unsuspecting facility owners. We have found from experience that factory calibrations of detectors are often not sufficiently accurate for use in systems in actual deployment. There are many reasons for this. One problem seems to arise in regard to detector response *in-situ*; although detector design is certainly well established, we have seen cases where there seemed to be little cognizance on the part of a manufacturer of the variety of factors which may affect detector response within a functioning exhaust system. More than one detection system manufacturer has claimed to us that their systems were precalibrated for all nuclides, had linear response over the range of interest, and/or needed no on-site calibration. Upon testing, it was found in a number of instances that the manufacturer's calibrations were inaccurate by significant amounts, in at least one case egregiously so, apparently due to an error in the calculations used to generate the factory calibrations. Additionally, we have seen at least one system that was significantly nonlinear in its responses, and yet had no means by which to calibrate the nonlinearity into the sampling and reporting software, requiring users to perform numerous and onerous hand calculations. These are just a sampling of the many problems we have come across in actual installations. Regulators and facility operators should never simply presume that systems will operate as advertised.

Among the many variables that may affect both factory and on-site calibrations are the following:

- Questionable calibration techniques (i.e., using beta rather than positron emitters with inappropriate beta energies, using sealed sources rather than gas phase emitters for primary calibration, or other potentially inappropriate calibration modalities)
- Lack of consideration for variations in exhaust system design, such as flow rates and duct sizes, and how these variables may affect measurements
- Questionable system design parameters, such as sensitivity, range, saturation point, response time, collection interval, etc.
- Lack of consideration of adsorption effects in ducts and on detector housings and how they might affect detector response
- System elements (i.e., detectors, amplifiers, software, etc.) that are malfunctioning or do not perform to design specifications
- Errors in installation (i.e., placing detectors near filters in ducts, where they are guaranteed to be grossly affected by radiation from adsorbed nuclides)

As a matter of course in cyclotron permitting we have insisted upon the performance of *in-situ* calibrations using (at a minimum) one high- and one low-activity bolus of representative nuclides (i.e., PERs of appropriate positron energies, preferably chosen from among those to be detected). Bolus nuclides for release should be chosen, if at all possible, from one or more of the nuclides that will be released via the exhaust stream. If multiple nuclides are to be generated, release of a single nuclide for calibration of monitoring systems relying upon positron detection is probably adequate, as long as its maximum and average positron energies are reasonably representative of the other nuclides to be released. Systems relying upon 511 keV annihilation gamma detection in most cases can be calibrated with any conveniently utilized positron emitter. Bolus activities chosen for release should be representative of the estimated minimum and maximum actual release activities per run.

Nuclide release should mimic actual release conditions; most particularly, in that releases should occur over a time frame representative of the conditions encountered at the site. Releasing a nuclide all at once simulates a rupture event, but may produce unrealistic airstream concentrations in relation to more typical, extended releases. One simple method for producing a controlled release uses $^{11}\text{CO}_2$. A coil of copper tubing, sealed at one end, is fabricated to be small enough to fit into a dose calibrator. The coil is submerged in liquid nitrogen; at the same time, the carbon dioxide is introduced into the coil. The $^{11}\text{CO}_2$ will condense onto the tubing wall, whereupon the coil is capped, put into the dose calibrator, surveyed for

activity, and then removed to the hot cell, whereupon it slowly releases the carbon dioxide as it warms. This method is simple, fast, and inexpensive to perform.

The choice of how many releases to perform will be dependent upon results and needs. Our practice has been to insist upon one release each of high and low activity, in order to simulate the full range of releases expected during routine operations. The resulting calibration curve (obviously linear in this case, with only two points of measurement) is then compared with the manufacturer's calibration curve (which are generally linear over the region of interest). If the slope of the observed calibration curve matches that supplied by the manufacturer, it should be reasonable to presume that the observed response is also fairly linear, and that two releases will be sufficient for an initial calibration. In this case an adjustment will only need to be made for differences in the intercept of the calibration line. If the manufacturer's response curve is nonlinear, or if there is reason to suspect that the measured response is nonlinear, then more releases of appropriate magnitude will need to be performed, and a calibration curve generated. (It should be noted that while most manufacturers in our experience state that their detector responses are linear, we have found that they are often not; we have heard at least two reports of logarithmic response curves for NaI detectors over observed detection intervals).

Recalibration should be performed regularly; the optimum frequency for recalibration is debatable, but we believe that annual (or at the very least biannual) recalibration is a necessity, given the possibility for drift and other problems in detection systems. Calibration checks using sealed sources of appropriate geometries is a reasonable method by which system response may be confirmed between primary calibrations.

These real-time detection systems will (or should) utilize real-time flow-rate detection using either primary or secondary standards. Pitot static tubes are commonly used, and once installed correctly require no calibration. Heated element (hot wire) anemometers are also popular; *heated element* is a better description than *hot wire*, as some of these devices use elements that are decidedly not wire-like, such as thermocouples. It is essential that these secondary standards be calibrated against primary standards on a regular basis. Most detection systems will automatically integrate the flow rate readings into release calculations.

PUBLIC DOSE MODELING AND ESTIMATION

Because of the potential magnitude of discharges of PERs to the environment from cyclotrons can exceed the average annual effluent concentration values listed in Table II, Column 1 of the federal and state regulations, regulators will generally need to rely upon dose modeling when evaluating potential doses to the public from these emissions. A familiarity with the basic equations of atmospheric dose modeling and with common modeling software is essential. Because the location of these facilities is often in the hearts of highly populated areas, their siting and licensing may be subject to a great deal of public scrutiny. Environmental dose measurement can function as an invaluable adjunct to dose modeling, once a facility has been operational for a period of time, both as a physical demonstration of compliance with dose limits, and to confirm the extremely conservative nature of correctly performed dose modeling.

ENGINEERING AND DESIGN FACTORS AFFECTING SOURCE TERMS

There are many factors related to system installation and design that can affect dose received by a public receptor. Each of these will need to be considered by the facility owner during the design stage, and by the regulator when evaluating ALARA and dose considerations. It is strongly recommended that regulators become involved with the radiation safety aspects of facility design and planning as early as possible. We routinely request attendance at planning and progress meetings for large facilities and review design plans for smaller ones; pre-permitting inspections have also proven invaluable. Health physics regulatory concerns are often poorly considered (or entirely unconsidered) by facility owners and designers, and health physics staff members are not always adequately knowledgeable about these issues or involved in the early stages of facility design. Redesign and retrofitting conflicts are not only costly monetarily, but also politically and in terms of goodwill, and are easily avoided once facility owners realize that an early interest in regulatory compliance is in their best interest, as well as that of the regulator and the public. Emphasis

on the fact that early consideration of regulatory concerns saves time and money usually brings willing cooperation on the part of facility owners and operators.

Flow rate, stack height and momentum rise

Stack height is an important factor in dose modeling and received dose. Increasing stack height increases the distance from exhaust point to receptors (in most instances), decreases the potential effects of stack-tip downwash, and tends to minimize entrainment and stagnant zone effects on nearby surfaces of buildings (see modeling below for mathematical treatments).

Flow rate has an immediate effect upon dose parameters in some systems. Flow rates should be checked upon installation by a certified contractor and at reasonable intervals thereafter. Most cyclotrons will have real-time effluent flow monitoring; regulators should be aware of the possibility of improper installation of Pitot tubes (i.e., tubes improperly located in the duct, either diametrically or too close to elbows or other flow-influencing obstructions).

The slower the flow, the more time there is for decay to occur; this may be of consequence for very long exhaust stacks and short half-life PERs such as ^{15}O , and may be taken into consideration when performing dose calculations. Conversely, the higher the flow rate, the higher the potential *momentum rise* of the plume if there is no exhaust cap at the stack exit. Momentum rise increases the effective height of the exhaust stack. It may be increased greatly through the use of an auxiliary exhaust fan (“air cannon”) located at the stack exit; this is highly desirable for installations in “urban canyons” such as occur in cities like New York, which have mixtures of very large and very small buildings sitting side by side. Mathematical modeling of momentum rise is considered below.

Finally, not to be overlooked is the fact that fans and mechanical ventilation linkages require regular maintenance. This fact is not known by many facility operators, but is established practice in industrial hygiene.¹⁰ Routine maintenance of these items should be a part of all regulatory compliance agreements.

Stackhead and weather caps

Stackhead construction is very important in regard to pollutant dispersion, and yet is seldom considered by facility planners. Almost always to be preferred is a *vertical discharge cap*; this is a simple stack cap that allows air entrainment and precipitation loss at the bottom. Using this type of cap, at 12 diameters height above the exit point, discharge velocity will still be roughly 50% of that at the exit, facilitating dispersion.¹¹ The more commonly used *weather caps* deflect discharges downward, generally toward receptors, and encourage entrainment along roof surfaces and vertical walls. As long as a vertical discharge cap is used, weather caps are usually not needed for an exhaust that is always discharging air, as is the case with cyclotron facilities. If water infiltration is a real concern, the use of offset stacks is to be encouraged.

Stack location

The importance of stack location seems to be another item routinely overlooked by facility planners. Often a seemingly minor relocation can make a huge difference in dose to receptors. Some factors to keep in mind when evaluating stack location are the following (please keep in mind that these are generalities, that there are always exceptions, and that proper professional judgment needs to be independently exercised in every case).

Height. If the total stack height is more than 2.5 times the height of the building it is on, in most cases there will be no wake effects (where the exhaust stream is entrained into the wake behind the building), little chance of entrainment into building air intakes on the roof, and no local stagnant zones near the building. Obviously, for a variety of reasons, this configuration is often not feasible. For lower stack heights, it is often prudent to take no advantage of height above grade in dose calculations; nevertheless, as mentioned previously, generally the further away the exit point is from the roof and air intakes, the better.

Offset from a vertical wall. Location of a short stack along a vertical wall may encourage entrainment in building wakes and higher concentrations along the wall.

Location near air intakes. Intakes located on vertical surfaces of buildings are often ignored during facility planning and dose modeling, as the possibility of wake effects is seldom considered.

Obstructions and nearby tall buildings. Again often ignored is the fact that nearby buildings and obstructions affect airflow, often in unpredictable ways. A building in or near the path of flow will affect flow patterns; eddies and stagnant areas are likely to arise, and calculations should account for the likely formation of these phenomena.

Micrometeorology. Wind speed and direction are enormously important dose factors, and vary widely according to location. Wind speed generally picks up near rooftops because of the Bernoulli effect. The default wind speed for dispersion calculations is often taken to be 2 m/s; if concrete evidence exists that wind speed is higher (or lower), this should be taken into account. Wind direction is all important as well; calculations of dose at each receptor should always take into account the proportion of time the wind is expected to blow in that direction if possible. The program CAP88-PC already contains wind speed and direction information for many airports around the country. If a building is in a fairly open area, not too far from the city airport, and not affected by local factors (buildings, valleys, obstructions, etc.) then these wind data compilations may be very useful. Local conditions should always be evaluated whenever possible; wind data is easily accumulated through the use of a digital weather station. The price of a simple station usually starts at around \$1000.00; given the total cost of many cyclotron facilities, this is a minor expense indeed. If evaluation of on-site weather conditions is not feasible, local data may be available from the National Climatic Data Center in Asheville, North Carolina, where data is available for several hundred locations around the country. Finally, if the necessary information is not available through these means, dose estimates will need to be performed using highly conservative estimates of these parameters.

ATMOSPHERIC TRANSPORT AND DISPERSION MODELS

Dispersion models are used to calculate the concentrations of exhaust products downstream from their release point, once release concentration is known from direct measurement or prospectively estimated by mass-balance calculations. The models to be used in this capacity will be those appropriate for long-term releases from point sources, to receptors located on flat terrain; the time frame over which exposure is to be considered will generally be yearly. These models are not appropriate for short-term releases, nor should they be used to back-calculate releases from air concentrations. Also, it is obvious that none of calculational models that follow account for radioactive decay, or plume depletion by precipitation scavenging or deposition. After choosing and applying the appropriate model(s), the average yearly nuclide concentrations obtained at nearby receptors can be estimated. The concentrations at the receptor sites are then used to calculate potential dose through the use of dose conversion factors obtainable through EPA's Federal Guidance Report No. 11¹² or NCRP Report No. 123 II.¹³ (computer programs such as COMPLY and CAP-88PC perform this step automatically). A selection of useful mathematical models and programs for PC-compatible computers is presented below as reference; their sources of origin are indicated by the associated reference numbers. We cannot emphasize enough that it is essential to study and understand the theory and use of atmospheric dispersion estimates *before* using these models in order to ensure proper application; the notes following each description are not sufficient to ensure that usage will be appropriate in all instances. Because of space limitations, it is impossible to detail here all information that one should know about these equations and their use. We have found Turner's work on atmospheric dispersion estimates,¹⁴ as well as NCRP Report No. 123 I,¹⁴ to be invaluable references; doubtless there are many others. Users' guides for the computer programs mentioned below should be read thoroughly, as misapplication of the results of these programs seems to be common as well. An in-depth understanding of the appropriate application of the models and interpretations of results is necessary on the part of both the applicant and the regulator.

Concentration at stack exit point¹⁵

The simplest, and generally least applicable, model assumes that the effluent concentration C at the receptor will be the same as that at the stack exit:

$$C = \frac{fQ}{V} \quad (1)$$

where

C = average annual concentration (Bq/m³)
 f = fraction of time wind blows toward receptor
 Q = effluent release rate (Bq/s)
 V = flow rate at exit (m³/s)

Concentration using a basic Gaussian plume model^{16,17}

The Gaussian distribution is a type of relationship from statistics that describes the frequency of occurrence of many types of physical or statistical events. This distribution (also called the normal distribution or bell curve) describes such things as the way height or IQ vary in large populations, or the way errors tend to occur in random observations (this is what Gauss is reputed to have been describing when he derived the equation). It is found that the distribution of a gaseous pollutant in air can be described using Gaussian mathematics, given that you know some facts about the situation (such as the rate at which the pollutant is entering the atmosphere, how fast the air parcel is traveling at the exit point, the direction in which the wind is blowing in, etc.).

The equations presented here are each suitable to calculate the concentration of a radionuclide under a particular set of circumstances; initial conditions are extremely important for determining which equation to use. Note that all of these equations are best estimates, not to be considered accurate for any particular circumstance; they are simply convenient modeling tools, that if used conservatively provide *reasonable upper bounds* on nuclide concentrations at receptors, and therefore on acquired dose. If there is any uncertainty about which equation is appropriate in a particular case, or how to apply them, consult a modeling expert; misapplied equations can generate sizable errors. The more general (and more complex) equation presented here is often not needed for dose modeling, but familiarity with it and how it works is important; see the references for this section or other dispersion texts for more detailed information.

One of the basic forms of the Gaussian dispersion model is

$$C = \frac{fQ}{\pi u \sigma_y \sigma_z} \exp \left[-\frac{1}{2} \left(\frac{H}{\sigma_z} \right)^2 \right] \quad (2)$$

where one may generally take σ_y and σ_z as

$$\sigma_y = \frac{0.08x}{\sqrt{1 + 0.0001x}}$$

$$\sigma_z = \frac{0.06x}{\sqrt{1 + 0.0015x}}$$

for neutral atmospheric stability conditions. Here:

u = mean wind speed (m/s)
 H = height of release point (m)
 x = horizontal distance from release to receptor
 σ_y, σ_z = the horizontal and vertical turbulent diffusion (Pasquill-Gifford) parameters respectively (in units of m), which are functions of the atmospheric stability and distance to receptor

This equation is used to calculate concentration for receptors at ground level, directly below the plume centerline. The Pasquill-Gifford parameters presented here are applicable to rural, unobstructed conditions, and can be determined for various stability conditions of the atmosphere. Stability is rated from A (unstable) through F (very stable); neutral conditions are D class. Plots and equations for these parameters are available in Turner, along with detailed limitations on their usage.¹⁸ Continuous emissions and steady-state conditions are presumed, as are conservation of mass (no settling, reactions, decay, etc.), wind always in x direction, and, of course, that Gaussian conditions prevail for dispersion. This equation may be grossly inaccurate at extreme distances (tens of kilometers) or under extreme atmospheric conditions.

Wake effects¹⁹

For a given building height h_b , if the stack height $H > 2.5h_b$ and there are no nearby buildings influencing the flow then the source may be considered to be isolated from its building support, and there will be no building wake effects to modify flow. In this case Eq. (1) above may be used, modified by appropriate wind direction and frequency data if available. If $H < 2.5h_b$ then the plume exiting from the stack may be entrained into the wake behind the building. To account for this possibility, when $H < 2.5h_b$ we presume that $H = 0$.

The stack height H should often be taken as zero, or a minimal value such as 1 m, in instances where receptors will (or might) be above ground level, or when wake effects may pertain (see below); assuming this value to be minimal is generally a prudent conservative assumption, unless H is quite considerable in relation to its surroundings.

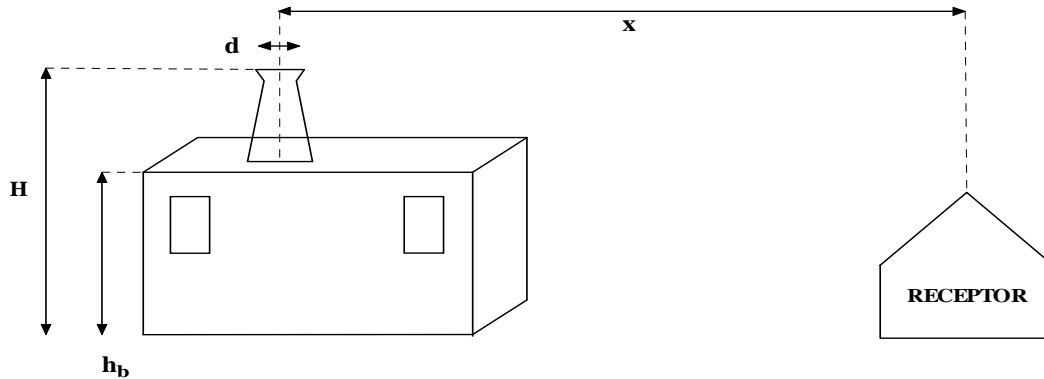


Figure 1. Parameters for dispersion calculations

Source and receptor located on same building surface²⁰

If the source and the receptor are on the same building surface (roof or side of building) and $x \leq 3$ times the diameter of the stack, it should be presumed that the receptor is breathing undiluted exhaust and Eq. 1 should be used. If $x > 3d$ then

$$C = \frac{30Q}{ux^2} \quad (3)$$

where u = the average wind speed (m/s) at roof level measured far enough away that the Bernoulli wind-increasing effect over the building will not affect the result. This equation accounts for buildup of concentration along a vertical wall due to the building wake effect.

Source and receptor not on same building surface²¹

We wish to find concentration when a receptor is not on the source building, but stands close by on the ground or in a courtyard. Consider the source building: it will present a certain surface area perpendicular to the direction of airflow. This cross-sectional area is called the *projected frontal area* and is represented by A_{cross} (see Fig. 2). When $x \leq (A_{\text{cross}})^{1/2}$ or $x \leq 100$ m, we may use the following equation:

$$C = \frac{fQ}{\pi u h k} \quad (3)$$

where $k = 1$ m and h is the *smaller* value of the height of the building h_b or the cross-sectional length h_{cross} .

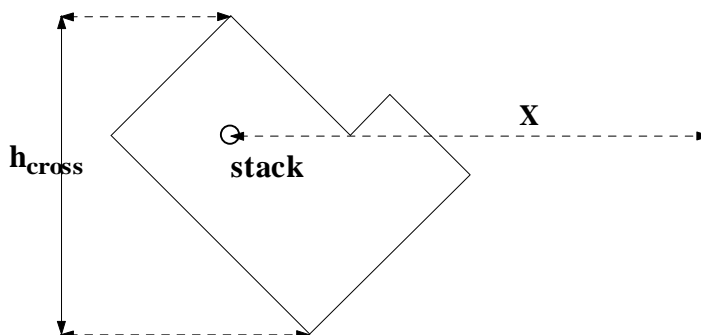


Figure 2. Determination of cross-sectional length h_{cross}

For the condition where $x > 100$ m, and it is thought that airflow is still affected by building wakes, calculational decisions will need to be made. Air concentrations and concomitant dose for filterable nuclides from cyclotrons may well have already reached their maximum somewhere before $x = 100$ m, or it may be possible to demonstrate that dose will remain below regulatory limits at all distances, in which case the methods described will probably suffice. If not, one can resort to the use of somewhat more complicated calculations to describe the situation which occurs in urban areas or those with increased mechanical and/or buoyant turbulence. See NCRP Report 123²² or Turner²³ for applicable procedures.

Momentum rise

Often overlooked when performing dose calculations is the fact that the exhaust airstream may rise considerable distances above the stack exit before effective dispersion begins. In this situation it may be considered that the height of the release stack has effectively been increased, and this fact may be taken advantage of when performing dispersion calculations. Emission height may be affected by two factors. The one that may be encountered with cyclotron facilities is known as *momentum rise*, and is the extra height an exhaust stream will attain because of the momentum of the airstream coming out of the stack. This may or may not be considerable, depending upon site parameters and whether or not an air cannon is used to increase momentum rise. The other factor to consider is whether the exiting airstream is heated above the temperature of the surrounding air parcel; if it is, the exit stream will rise because of its buoyancy. Because cyclotron exhausts are seldom if ever at temperatures significantly higher than ambient, buoyancy rise will not be considered here.

Exit velocity will vary greatly depending upon exhaust system design. For routinely encountered systems, where linear exit velocity (commonly measured in ft/min) may be modest, say, something of the order of 200-300 ft/min (roughly 1.0-1.5 m/s), momentum rise will not be very significant, and can be ignored for conservatism. In crowded urban areas with many large buildings downstream, use of an air cannon can add 70 m or more to the stack exit height, and is an effective and relatively inexpensive means by which to increase this factor.

To calculate momentum rise, we use equations for rise under both stable, and stable-neutral, conditions and then use the lesser value as the presumed rise.²⁴

$$\text{stable rise: } \Delta H = 1.5s^{-1/6} \left[\frac{(v^2 - d^2 T)}{4T_s u} \right]^{1/3} \quad (4)$$

$$\text{unstable-neutral rise: } \Delta H = \frac{3dv}{u}$$

Here

ΔH = change in effective stack height (m)
 u = wind speed at stack exit point (m/s)
 v = stack gas exit velocity (m/s)
 d = stack exit diameter (m)
 T = ambient temperature (K)
 T_s = stack gas temperature (K)

The parameter s is called the stability parameter and can be calculated by

$$s = \frac{g}{T} \left(\frac{dT}{dz} + \Gamma \right) \quad (5)$$

where g = acceleration of gravity (9.8 m/s^2) and Γ = adiabatic lapse rate (0.0098 K/m).

Stack-tip downwash

There is another adjustment that can be made to stack height because of an effect called *stack-tip downwash*. This is a fluid-dynamical effect that is the result of vortex formation in the downwind direction. When the ratio $v/u < 1.5$, the emitted stack gas may be pulled down somewhat because of eddy formation. If h is the height of the stack, to calculate the revised height of emission h' , we use the equation²⁵

$$h' = h + 2 \left(\frac{v}{u} - 1.5 \right) \quad (6)$$

The maximum correction factor is $3d$; in many cases this effect is therefore negligible. The final effective height will thus be the height of the stack, plus the momentum rise, minus the stack-tip downwash for most cyclotron installations.

Computer programs for performing dose calculations

A number of IBM PC-compatible programs exist for the calculation of concentration, dose and risk to the nearest receptor and/or population. Two of these have been created by federal agencies for use by health physicists for dose modeling, are free for use, and are frequently encountered for modeling releases from cyclotron stacks: CAP88 PC²⁶ and COMPLY.²⁷ Both programs have firm limitations of applicability; these limitations are very often not understood by applicants. A brief overview of their functionality is presented below. In this regard some caveats are necessary: the few salient facts presented about these programs below are abbreviated, incomplete, and presented for convenience only, and are not intended to replace program documentation or experience in use. The user guides must be read before application, and the programs and their results should only be used or evaluated by health physicists experienced in dose assessment.

It is important to note that both programs are intended only for modeling low-level chronic exposures, and that they are based on the Gaussian plume model of dispersion with its associated limitations. Presumably

these programs will be used only to model dose to the nearest receptor in order to determine compliance with regulations; features related to population dose and risk are not considered below.

CAP88-PC. This program can perform dose and risk assessments for collective populations and maximally exposed individuals. A convenient feature is the presence within the program of meteorological data for many National Weather Service stations; they include direction, frequency and stability data. CAP88PC calculates momentum and buoyancy rise, and also calculates radionuclide plume depletion; it does not calculate stack-tip downwash, or building wake situations where the receptor is located on or near the source building. (Stack-tip downwash and building wake can be taken into account simply by discounting the height of the stack; this can be done by using zero or 1 m for the stack height.) Also note that the dispersion coefficients used are for open country, not urban or suburban areas or those of irregular topology, and results must be considered in this light. The effective dose equivalent for the maximally-exposed individual is tabulated in mrem/yr for a 50 year exposure. Reference 26 contains the World-Wide Web universal resource locator for downloading this resource.

COMPLY. COMPLY was developed by the EPA to demonstrate compliance with National Emission Standards for Hazardous Air Pollutants (NESHAPs) in 40 CFR 61. It is a Gaussian plume model similar to CAP88-PC, and most of the comments for that program above apply to the use of this program. Notable differences are that COMPLY does consider building wake effects, while not considering stack-tip downwash. Reference 27 contains the World-Wide Web universal resource locator for downloading this resource and for further information.

DIRECT MEASUREMENT OF DOSE

Dose modeling is ultimately a best guess at maximum exposure to public receptors. In many (or most) cases, a well designed modeling effort will substantially overestimate actual dose to the most affected receptor—modeling should be a conservative exercise, and while realistic assumptions are desirable, it behooves the regulator to always err on the side of overestimation. Additionally, it is to be remembered that no model accurately reflects actual “microconditions” at the site being considered. In order to demonstrate compliance with dose regulations, it may be desirable to conduct direct measurement of dose.

Given the concern that may be expressed by the public, it can be very helpful to both regulator and regulated entity to be able to present physical evidence that received doses are within regulatory limits (or, often, unmeasurable). Environmental dosimetry of sufficient sensitivity for regulatory purposes is currently easy to perform and relatively inexpensive given the availability of environmental-level thermoluminescent dosimeters (TLDs). Landauer Inc.²⁸ produces environmental-level TLDs that utilize aluminum oxide ($\text{Al}_2\text{O}_3\text{:C}$) as a detection medium. These dosimeters are read by laser using optically stimulated luminescence; the medium luminesces proportionally to dose. Landauer claims that minimum detectable dose is nominally 0.1 mrem ambient dose equivalent, that response is linear to 100 mrem, and that fading is less than 10% during three months of extreme environmental conditions. Other methods for environmental dosimetry are, of course, available, but given their costs (in terms of money, tradeoffs and effort) they are often impracticable.

Whenever measuring low levels of man-made radiation in the ambient radiation field, one must deal with the fact that background radiation levels are large in comparison with measured dose. If background could be counted upon to be fairly uniform, even small doses to receptors would be apparent, but background measurements with high-sensitivity TLDs are subject to considerable variation. Interpretation needs to consider many factors, some of which change unpredictably. Most terrestrial background radiation comes from ^{40}K , from radionuclides in the uranium and thorium decay chains, from radon daughters and cosmic and cosmogenic sources, and from radionuclides deposited as a result of nuclear weapons testing. Radiation levels can vary very significantly due to geographic, temporal, meteorological and even astrophysical factors. Correct interpretation of measurements requires familiarity with these local factors, which can only be gained through the implementation of a well planned, and unrushed, assessment of radiological background. Regulators must also be on the lookout not only for poor placement of measurement TLDs, but for improperly placed control dosimeters as well. Given these potential difficulties, TLD readings in some cases may have to be regarded as confirmatory rather than quantitative.

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PET Site Planning

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INTRODUCTION

The use of positron emission tomography (PET) as a clinical and research imaging tool is rapidly expanding. However, the creation of a new PET facility is a difficult and challenging prospect. In addition to the many details that have to be considered, there is the additional problem that relatively few individuals have any experience in constructing such a site. As a result, one cannot rely on the architects or contractors to fill in the details. Each phase of the planning has to be carefully checked to insure that all the involved people are aware of the special problems posed by a PET facility. Often this will require the services of a PET consultant.

Careful planning is the key to a PET facility that will meet the present and future needs of the users. The planning process usually takes one to two years. Much of this time is spent in securing funds, selecting equipment, securing a consortium of users, in addition to interacting with architects. One obvious fundamental step of the planning process is frequently neglected and that is a formulation of the PET program's goals and objectives. The amount of space, utilities, computer facilities and support staff are all highly dependent on the major thrust of the program. It is also necessary to project long term goals so that adequate space for expansion is contiguous with the initial PET facility.

PROGRAM GOALS

As stated above, the program goals and objectives will determine the necessary equipment and space needed for the PET facility. As a result, special attention must be given to formulating goals that are consistent with the support and resources available at the institution. Typically, PET centers that have been developed in the last several years fall into four distinct categories.

- I. Clinical PET with no radionuclide production facility. This center has no cyclotron. All the radiopharmaceuticals are either generator produced or are purchased from a local distribution center. There is no involvement with basic research and there is complete reliance on the equipment vendor for new upgrades and capabilities.
- II. Clinical PET with radionuclide production facility. This center has a cyclotron and some type of automated chemistry synthesis. There is little involvement with basic research and there is complete reliance on the vendor for new upgrades and capabilities.
- III. Clinical PET with research support staff. Along with a cyclotron and automated chemical synthesis, this center has a scientific support staff of a chemist(s) and physicist(s) capable of developing PET procedures and radiopharmaceuticals that have been described in the medical literature. The major emphasis is to perform routine patient studies, but some independent research is carried out.
- IV. Research PET facility. Along with the PET scanner and cyclotron, this center will have a research team of scientists performing basic research on developing new agents and procedures. Considerable space is allocated for laboratories and animal facilities.

Because of the expense of developing new facilities, few institutions have the resources to build a complete center all at once. In the planning processes, allow for provisions to acquire appropriate additional space, access to that space, and utility support which consists of air handling, hot cell exhaust, power, chilled water and so on to achieve this overall expansion of the program goals. Some of the activities that are necessary for a PET research center may not be consistent with guidelines of local hospitals such as animal and biodistribution studies. It is relatively easy to add clinical capabilities to a

program initially defined for only research. It is much more difficult to provide the opposite capability.

It is also important to have sharply defined goals that are focused specifically on PET. Some institutions will invest in a cyclotron believing that they can use it for the production of conventional nuclear medicine radionuclides or neutron therapy as well as PET. Experience has shown that this seldom, if ever, works successfully.

Lastly, when developing the center's goals, care should be exercised to match the facility resources and expertise with realistic expectations for type and number of studies performed. Qualitative PET imaging is less stringent on radiopharmaceuticals delivery schedules, utilizes well established positron labeled agents, and does not require arterial blood sampling. Quantitative PET requires rigorous quality assurance to insure the best possible accuracy of the technique, routine arterial blood sampling, and flexible schedules for study performance. Often multiple agents will be prepared and sequential studies performed on the same patient (test/retest). Extra time is required to educate the patient/volunteer and family about a research study. Studies may last longer in order to acquire a full range of dynamic PET data (uptake and washout). Metabolite determination is necessary to quantify agents that undergo active breakdown of the PET label from the injected radiopharmaceuticals. It is not uncommon to perform only two (2) research studies in an eight hour day whether they be human or animal studies. Automated radiopharmaceuticals syntheses help to reduce personnel needs and streamline PET studies. Scheduling syntheses, patients, and computer time all require many unrelated operations to perform faultlessly. Problems still occur. It is unlikely in the near future that more than four (4) routine heart and/or brain studies will be performed in an 8 hour day. Therefore, in the planning process determine the needs of the clinical and research community for PET studies. Discuss the ability to perform these studies in their entirety with PET centers that already have considerable experience. Then critically evaluate how many PET studies your center is likely to perform. By initially exaggerating the number of predicted PET studies, the ability of the new PET center to adequately cope with start-up problems and expansion problems may be significantly compromised.

FACILITIES AND SPACE

The size and functional use of space in a new PET center is determined by the program goals, financing, new construction or remodeling of existing space and contiguity of space. At present, it generally costs \$150/sq. ft. to finish construction of specialty laboratory space from shell (guttled if old construction) space. This does not include the fabrication of a new building. The costs of renovating existing space may or may not be less than new construction, when demolition, asbestos removal, inadequate floor loading, limited access for equipment and upgrades to comply with building codes must be addressed. It is generally better to have new PET centers in close proximity to patient care areas for both in- and outpatient access. If the PET center is located in research buildings which are not currently used for patient care, specific hospital codes must be adhered to in upgrading the PET space as well as patient access such as corridors, elevators, and so on. In the plan for new construction, renovation, or future expansion, it is best to keep all PET space contiguous and on one level. Insure that access routes remain to accommodate acquisition of additional PET tomographs and other equipment. This centralizes functions, limits radiation protection problems associated with transport of radioactivity, and keeps the staff together as a unit. These features tend to enhance overall center efficiency and productivity, and will minimize the duplication of equipment and personnel at different sites.

There are five functional areas to be considered during space planning. These include radionuclide production, radiopharmaceuticals synthesis, PET scanning, support laboratories, radiation protection, and miscellaneous (that is, everything else). Functional descriptions of the space follow which also include comments as to types of equipment to be located in each of these areas.

Radionuclide Production

A. Cyclotron Shield

Currently, the most acceptable accelerator to produce PET radionuclides is a small cyclotron with fixed energies. Protons and/or deuterons are accelerated. Extracted beam currents are between 50-100 μ A. In all cases, high energy neutron and gamma radiation are produced when the

cyclotron beam interacts with metal parts within the cyclotron, with targets, or with the shield itself. It is the job of the radiation shield to attenuate the radiation exposure produced from particle bombardment to acceptable levels in the most efficient fashion. This is accomplished by either directly shielding the cyclotron (self-shielding) or by placing the cyclotron in a thick walled room (vault). The costs of the self-shield are fixed, since the manufacturer knows the orientation and intensity of the radiation field of a particular cyclotron run at the maximum extracted beam current, and can design the shield accordingly. The shield completely encapsulates the cyclotron during operation, but can slide away on tracks or grooves to permit access for maintenance. Hydraulic pistons are used to move the heavy shield. The room containing the self-shielded cyclotron must be large enough to contain some maintenance areas for targets and the cyclotron (tools, work benches, leak detector), chilled water recirculation system, power supplies, gas cylinders, and perhaps air compressors or other equipment. Further, the room must permit access to this equipment when the shield is retracted. When the self-shield is closed, workers can be present in the room while the cyclotron is on and producing radioactivity.

The vault design is usually more costly than the self-shielded design, but provides much better access to the cyclotron for maintenance, upgrades and expansion. If the vault is sufficiently large, even a second cyclotron, it warranted by the program activities, can be added with minimal additional costs for shielding, safety systems, and radionuclide delivery. Equipment needed to synthesize various precursors can be mounted on the wall in the vault which provides for good access for maintenance. In the self-shielded setting, all syntheses must be performed in a shielded area such as a hot cell. The vault provides an excellent location to store activated cyclotron and target components such as beam extractors, dees, target bodies and foils. Suitable storage must be designed for these products associated with all cyclotron operation in the self-shielded version. The design of the vault is less standard than the self-shield since the orientation of the cyclotron and targets with respect to the vault access is user-defined. Access may be in the form of a maze or a plug door. Greater space utilization is achieved with a plug door, but simpler; maintenance free, less costly vault access is achieved with the maze design. Air handling, water cooling, conduits for nuclide transport and the vault access require that the vault radiation shield be specifically tailored for each user site. In general, the vault is a better choice for the research environment because of the flexibility and overall access it allows, while the self-shield is preferred in a routine clinical setting because of its simplicity, compactness, and price.

B. Power Supplies and Water Cooling

Cyclotrons require numerous power supplies to operate the main magnet, RF acceleration, ion source, and other equipment. These systems should be located in a low radiation area so that they can be easily maintained. Cable-ways or conduits between the cyclotron and power supplies are necessary to connect the cyclotron to the power supplies. A deionized, closed loop recirculating chilled water system is required to cool the cyclotron. A source of year-round primary water cooling is essential to maintain the closed loop system temperature between 55° and 60°F (13° and 16°C). These systems utilize space in either the room containing the shielded cyclotron or in a separate room that adjoins the vault. Close proximity to the cyclotron is desirable to reduce cable and tube lengths.

C. Cyclotron Control Room

Most new PET cyclotrons are completely operated under computer control and a dedicated room for cyclotron control is no longer needed. Cyclotron operations can be integrated into the entire facility computer systems which will permit operation of the cyclotron from the PET tomograph control room, the radiochemistry lab, the power supply room or cyclotron room if self-shielded. This concept decreases space requirements and puts control where needed most, thereby better utilizing PET center personnel.

Radiopharmaceuticals Production

A. Radiochemistry Laboratory

Processing positron precursors into clinically useful PET radiopharmaceuticals occurs in the radiochemistry lab. For clinical facilities in which there is limited development of new PET agents, this lab is mostly used for quality assurance testing for sterility, for pyrogens, and for chemical, nuclidic and radiochemical purity. For research programs, the radiochemistry lab will require hot cells for developing and labeling compounds, as well as performing QA functions. These cells shield personnel from high levels ($> 2,000$ mCi of radioactivity). Two types of automated radiochemistry (black box and robotic) reduce the burden on the radiochemist by performing routine syntheses. Black box technology may reside in self-shielded enclosures near a self-shielded cyclotron or in a hot cell. Hot cells are normally used to shield robotic radiochemistry. Robotic radiochemistry mimics human motions in the performance of tasks and is therefore more flexible. Black box technology is somewhat simpler, takes up less space, can be self-shielded, has limited flexibility. In either case, sufficient space is needed for hot cells or black box chemistry. Space for storage of chemicals and reagents is necessary. Toxic and volatile materials must be placed in chemical storage lockers which may be either free standing or located under hoods (preferred location). Needless to say, all radiochemistry is performed in hot cells and shielded hoods. All nonradioactive chemistry (cold chemistry) is done in chemical hoods. Lab benches are only used for apparatus setup, instrumentation, etc., and never used for chemical synthesis. Planning for adequate hood space is essential. Appropriate space and routing for supply and exhaust air for hoods and hot cells is also critical to the design of the radiochemistry lab. Space under the hot cell can be used to store radioactive waste (extra Ge-68, hot needles, columns). Space for numerous gas cylinders, precision scales, vacuum pumps, and drying ovens is needed as is some location in the lab to perform record keeping and information logging. These functions are critical to comply with federal and local radiation safety regulations.

B. Quality Assurance (QA)

QA testing is best done in a small, but separate room that provides for isolation from chemical corrosives. Abundant clean electrical power is necessary to operate the computers associated with QA equipment such as gas chromatographs (GC), high pressure liquid chromatographs (HPLC), and thin layer chromatographs (TLC). A laminar flow hood is used to prepare clinical HPLC columns and other sterile procedures. A separate room guarantees minimal personnel traffic and provides a clean environment.

PET Scanning

A. PET Tomograph Room

All PET scanning is performed in the tomograph room which contains not only the PET scanner, but also the computer controlled couch, cabinets and shelves for storage and all support apparatus for PET procedures. Key to the scanner space is visualization of the patient. This is more difficult to achieve with whole body machines that are used for both brain and heart imaging. Usually, the orientation of the scanner that is best for patient observation for brain studies obscures the patient's head for heart scans. Sufficient space to permit access must be designed for bed travel through the scanner portal. A wide access door and space to maneuver is best for patient transport by bed or stretcher. Most clinical supplies related to patient studies are stored in the PET room for maximum availability. Space for a crash cart, EKG monitor, TV monitors for stimulation studies and gas dispensing systems must be provided. Complicated PET studies often require 5 or 6 people in attendance and space should be provided to accommodate staff. The tomograph room should have fluorescent lights for procedure work (arterial line placement) and dimmable, incandescent lights to minimize visual stimulation during PET scans. Sound proofing the walls and ceiling is critical for allowing control of the auditory environment. Continuous sheet flooring reduces the risk of accidental dose spillage from leaking into cracks and presenting high

background rates to the scanner and staff. This is not an extreme problem with very short half-life materials (O-15, N-13, C-11 and F-18), but may be critical if a phantom containing several millicuries of Ge-68 ($t_{1/2}=280$ days) is spilled. An overhead mechanism for hanging various apparatus is very useful. If the PET room abuts an outside wall, every effort should be made to provide a window for patient and staff morale. If quantitative PET studies are to be performed, access to both the right and left wrist of the patient with the blood sampling apparatus is necessary. A section of the PET room with access flooring (computer floor) provides a means for easily connecting the tomograph with its associated electronics and a mechanism for making new connections to support equipment as the need arises. Shielded space for storage of phantoms is necessary. Good temperature regulation is essential if tomograph stability is to be maintained. Operation under standard conditions with the door open, many staff, and additional equipment tends to rapidly overheat the PET room and cause detector drift.

B. Control Room - PET scanning

All PET study functions are directed from this room. The PET study is set up on computer terminals, data are reconstructed and displayed in the control room. The cyclotron may also be run from this area. Key design features include large glass windows, sliding doors, mini-blinds or curtains between glass to reduce lighting in the PET room, and computer flooring. Access should be available from this room to all PET tomograph rooms, hallway, computer room, patient prep room, and image analysis room. Sliding doors between rooms yield the greatest usable space without creating obstructions. No barriers should exist between the control room and any other room, hence, all computer flooring should be recessed. This central hub approach dramatically improves efficiency of PET studies and helps to permit a technologist to rapidly view many situations with ease. Large amounts of bench space for computer workstations, printers, monitors and writing should be included. Dimmable, incandescent track lighting is very useful for minimizing eye strain during long hours of CRT viewing.

C. Patient Preparation Room

A quiet room for placement of the arterial catheter and/or uptake of PET agents (such as 2FDG) is extremely useful in high throughput situations. Otherwise, the patient occupies the PET couch during the catheter placement, uptake and imaging, and limits the overall use of the scanner by not permitting patient overlap. Single sheet linoleum flooring is appropriate as with the PET room. A small bench with shelves provides storage for supplies.

D. Ancillary Blood Analysis

For quantitative PET imaging, space is needed to determine the content of radiopharmaceuticals and subsequent metabolites in blood. This requires automated and/or manual well counters, centrifuges and a microcomputer for data acquisition. For complex studies, multiple analyses may have to be performed on each blood sample. Plasma glucose analyzer and blood gas analyzer are also located in this room. As new quantitative studies are developed, analyses specific to each must be incorporated into the PET procedures that are currently performed.

E. PET Electronics and Computer Room

PET scanners require several cabinets of electronics to control and gather PET information. Front and rear access to cabinets is required for maintenance. A temperature and humidity controlled environment with HALON fire protection is best. Computer flooring provides easy access to lay cables between systems and provide power to each computer or cabinet. The tomograph control computer is also located here. However, as computer workstation technology advances, the need to provide significant space for computers is much less than it was even 5 years ago. Most workstations require only desktop space and no special environment. Space must be provided for power distribution and surge/spike protection equipment. Chilled air is provided by air conditioners and fan coil units when sufficient chilled water is supplied. These units must operate year-round. Most air conditioning units require at least twice the vendor specified floor space to provide

maintenance access, power and air handling connections. All too often, a computer room is designed for the appropriate tomograph and computer equipment without allowing adequate space for power distribution, air conditioning equipment and HALON fire extinguishing tanks. An emergency shutdown switch should be located by the doors to permit complete power cutoff in the event of fire or electrical hazard.

F. Image Processing Room

An image display and processing work area for technologists, PET staff, physicians and researchers is necessary. Tables with high speed, large display, workstations permit users to access current and archived data. Multimodality overlays (MRI, CT) and region-of-interest (ROI) workup is performed here; The number of work areas depends on throughput and type of PET program. High throughput and research sites necessarily need more image processing workstations than lower throughput programs. Computer flooring or cable trays provide the pathway for cable interconnectivity. Room dividers and local area incandescent, track lighting helps to provide some privacy and to eliminate CRT glare.

G. Additional PET Rooms

For centers anticipating future expansion and acquisition of more than one scanner, it is most advantage us to plan for that space while designing the new PET center. Having tomographs in two different locations detracts from center efficiency, reduces staff interactions amongst themselves and referring physicians, and necessarily costs more because of equipment duplication. Radiation protection issues become important when radioactivity must be transported from the cyclotron/radiochemistry lab to distant PET tomograph sites.

Support Laboratories and Shops

A. Cold Chemistry Lab

For research centers, it is important to be able to develop new PET agents. Much groundwork is needed before proceeding with radiochemistry. A small, but complete chemistry lab with multiple hoods is necessary.

B. Biodistribution Lab

Space for performing dosimetry and biodistribution studies is important. Animal work must precede human studies. FDA approval for INDs will not be granted without such work. The lab should be equipped with a small central operating table, automated well counters, and microcomputer data acquisition system.

C. Electronic/Physics Shop

In-house repair and fabrication of equipment can save substantial time and maintenance costs over service contracts. A small lab which includes high quality test equipment (oscilloscope, signal generators, low and high voltage power supplies, VOMs, OVMs, RE voltmeters, logic analyzer, frequency meter), as well as replacement parts (IC chips, resistors, capacitors, transistors, diodes, wire, etc.) and small hand tools is necessary. Vacuum equipment (vacuum pumps, gauges, connectors) and a helium leak detector are essential for diagnosing problems with the cyclotron vacuum and target pressure integrity.

D. Machine Shop

Repair of radioactive parts is more effectively achieved with an in-house machine shop. Tools to provide this service include milling machine, lathe, drill press, band saw, grinder, buffer, sandblaster, and welder. Stock supplies of some metal, plastics and wood are necessary as are nuts, bolts, screws, and Swagelok tube fittings. New equipment for automated chemistry, phantoms, animal apparatus, targets and detectors can be fabricated in conjunction with the

electronics/physics shop.

Miscellaneous

A. Offices

Office space should be provided for all major personnel within the PET center. If the staff are in close proximity to the action, reaction to problems is swift. Interaction with colleagues and referring clinicians stimulates an active dialogue to broaden the scope of PET scanning. The design should include extra office space to accommodate growth.

B. Conference Room

This space is multifunctional in that it is a local meeting room, lunch room, library, and, when placed back-to-back with the image processing room, allows on-line review of PET data for conferences and research meetings.

C. Reception and Waiting Area

An area is needed for family and friends to wait for the patient to complete the PET scan. Adequate space is more critical for multi-tomograph PET centers, high throughput centers, and those sites in which the PET facility does not adjoin other patient care areas, such as in a remote laboratory building.

D. Storage

Design for storage. No one ever does. You will need it.

E. Lavatory

Self explanatory.

F. Clean and Soiled Linen

For most self-sufficient clinical units, this is a requirement. For those centers adjacent to other clinical facilities, these rooms may be eliminated if routine access is permitted and functions shared.

Table 1.PET Space (in NET* square feet)

Space	Category++	I	II	III	IV
Cyclotron		-	450(SS)*	450(SS)	400(V)+
Power Supply/H ₂ O		-	-	-	400
Radiochemistry Lab		300**	300	400	500
QA Lab		-	100	175	250
PET Tomograph		300	300	400	500
PET Control		250	250	250	250
Patient Prep		120	120	120	120
Blood Analysis		-	-	150	250
Electronics/Computer		300	300	300	300
Image Processing		300	300	300	300
Cold Chem. Lab		-	-	-	600
Biodistribution		-	-	-	300
Electronic/Physics		-	-	200	500
Machine Shop		-	-	-	350
Offices		2x120	3x120	3x120	6x120
Conference		300	300	400	400
Reception		50	50	50	50
Waiting		100	120	120	100
Storage		100	100	200	300
Lavatory		50	50	50	50
Clean/Soiled Linen		100/100	100/100	100/100	100/100
TOTAL <u>NET</u> Square Feet		2,610	3,300	4,125	6,840

++ I=Simple Clinical, II=Complex Clinical, III=Clinical Research, IV=Research

* SS - Self shielded cyclotron room

+ V - cyclotron in vault, area is for interior of vault

** QA included in radiochemistry lab.

This does not include walls, utility closets, housekeeping space, corridors or any other nonfunctional PET space. This table does not include space for required air handling or other equipment designated as mechanical support facilities.

UTILITIES

There are several general utilities and services that must be supplied to the PET laboratories which include: room air handling (heating and cooling), chilled water cooling (cyclotron), air conditioning (computers and electronics), supply and return air (hot cells and hoods), power (surge protected and spike protected), vacuum, compressed air, distilled water, general and specialty gases.

Air handling should be made extremely simple for PET installations. Sophisticated heat recovery systems often employed in new structures, tends to make air balancing with hoods and hot cells almost impossible to achieve. If a radioactive gaseous release occurs, it is difficult to dilute and completely ventilate the contaminated environment. It is best to have the radiochemistry and cyclotron areas at lower pressure than other public areas (offices, corridors, etc.). Most offices and general laboratories usually have their doors ajar. Plan to ventilate hallways as well as rooms. Connections exist between various rooms, such as conduits, cable trays, and floor ducts. These all tend to invalidate air balance criteria. Interlock supply and exhaust fans for all hoods and hot cells to prevent the exhausting of the hood/hot cell environment into the laboratory in the event of exhaust fan failure. At least 10 air changes per hour should occur in the cyclotron room and at least 10-12 room air changes per hour in the radiochemistry lab. Care should be exercised to minimize drafts and high velocity air flow in the chemistry labs. Plan to accommodate more people and equipment to occupy rooms than original estimates. Expansion often occurs by adding staff and equipment but not space. Hence, design for sufficient room heat loading.

Failures often occur in room air conditioning for computers and electronics cabinets. Year round operation is difficult to achieve in northern climates. Size your air conditioning system to be no more than 2 times your total heat load. Too large an air conditioning system does not load it properly and will make it prone to failure. Too little air conditioning obviously will not meet your needs in the summer months.

Cyclotron heat loading is variable. Low loads exist round the clock for vacuum systems and high loads occur during cyclotron operation. Usually 50°F (10°C) input water to the primary side of a chilled water system is ideal for most situations. If year round building supplied chilled water is unavailable, a dedicated chilled water system must be installed. Great care should be taken to match the unit to the cyclotron heat load. Failure to do so, will cause inadequate cooling or excessive cooling, both of which lead to system failure.

Compressed air is required for operation of pneumatic valves. This should be dry, oil free, dust free, and operate at 100 psi and 10 cfm (cubic feet per minute). If pneumatic rabbit transport systems are used, sufficient ballast should be incorporated in the system (100-200 gal).

Clean, spike and surge free power is necessary for all systems. The computers and PET tomograph are particularly sensitive to power problems. With greater automation being used for cyclotron and radiochemistry, problems could also occur if particular attention is not given to electrical distribution in these areas.

Piping specialty gases around the radiochemistry and cold chemistry lab is very efficient, provided that all users can use the same pressure. Current chemistry lab requirements for special gases of high/low purity, special mixtures and so on, mean significant space is allocated to tank placement and storage. Rental charges on large numbers of tanks may be significant.

Communication is important in any type of PET center, with the implementation of current, single-line, phone systems, much utility of generalized user communication has been lost. Some type of voice activated intercom which permits connection to the phone system, multiuser connections (party line), paging, answer paging, and private communication is necessary. In some instances, portable FM transceivers are very helpful for maintenance tasks.

COMPUTERS

Computer systems for PET are rapidly changing. It is no longer necessary to construct a PET tomograph around a large CPU. It is more efficient and cost effective to employ distributed processing. High compute power now comes in small desk-top packages or workstations.

Air conditioning requirements specifically for computer rooms can be relaxed, since most of the cooling is needed for only the scanner electronics. Note that some of the heat burden once handled by computer room air conditioners must be borne by the overall cooling systems in offices and labs where workstations are now located.

All computer systems should be networked, preferably with Ethernet (IEEE 802.3) interfaces for highest image transfer throughput. This would include linking the PET tomograph acquisition and analysis workstations with cyclotron control, radiochemistry record keeping and data logging, remote data analysis sites and MRI and CT imaging systems for multimodality image processing.

It is also cost effective to use a single, dedicated, low cost, personal computer for monitoring the center's general facilities such as heating, cooling, power, radiation measurement, security, cyclotron vacuum, compressed air, water leaks, and so on. This computer can measure and record the status of all these systems. No major programming is required, given the large variety of software for data acquisition that is currently commercially available. If an out of bounds situation occurs, the computer can sound an alarm and even call or page appropriate people to alert them of the alarm condition. If no response from the user is received, it can institute a system shutdown. This greatly reduces system and center downtime by drawing attention to problems in a timely fashion, especially in a clinical setting.

Archival storage mechanisms are still developing, but two types of storage media have emerged as being very compact, robust, and easy to use. Small platter WORM (write once read many) optical disks and now erasable optical disks in the 650 MB size are particularly nice for backup and storage of patient information.

Though not excessively large in terms of storage capacity, the optical disk can be used by researchers to store significant portions of their research PET image data base. They can have the complete disk on-line whenever needed as opposed to spooling tapes or occupying large quantities of magnetic disk. New 8 mm magnetic tape is capable of storing 2.3 GB of data on a single \$10 cartridge. Hence, larger system backup is possible in a very compact package. It is fast by tape standards and convenient enough that multiple copies can be made for added security. The need is diminished for system backups that require several sequential tape mountings/dismounting and therefore eases the system manager's responsibilities. Unattended backup of large distributed systems are possible.

PET is totally acquired under computer control. Data are displayed on CRT screens. Limited hard-copy is needed. A permanent record in the patient's folder is useful. All other data for viewing and reading is more appropriately done from image processing workstations which permit on-line magnification, multimodality comparison, contrast enhancement and ROI analysis of functional images. By using optical disk storage, most archived data can be made readily available for simultaneous viewing of old and new studies. However, accurate and easy to use data basing is required to achieve rapid retrieval of archived studies. Object oriented data base software may prove to be the best mechanism for use in imaging situations.

On-line slide making capabilities is essential for the research environment. Current personal computer based systems are inexpensive and offer 4000 line resolution. Images can be easily transferred via the network to the slide processor for recording. Personal computer workstations are relatively inexpensive. Macintosh II and IBM AT or clones are suitable systems for remote data analysis and image viewing. Typically, the user needs to observe PET images in comparison with MRI and CT information. Region-of-interest (ROI) analysis is the next most common processing. These functions can be coupled with standard software functions as word processing, data basing, spread sheet and electronic mail, to develop a very powerful remote workstation. Network requirements must be met for this to be fast enough and truly useful. Data security and software management are problems at present, but software solutions are emerging to rectify deficiencies in these areas.

Array processor technology may be replaced by RISC (reduced instruction set computer) architecture. RISC machines already are within the 20-40 MIPs (million instructions per second) range and are quite inexpensive. They are much easier to program, require less code development, can be readily attached to a network, and with a generic user interface (Windows-X) it becomes possible to use machines at different locations with different operation systems very efficiently.

RADIOPHARMACEUTICALS TRANSPORT

In all cases, materials need to be moved from the targets to the hot cell or black box enclosures. Simple transport is accomplished by driving the materials (gas or liquid) with an appropriate gas (He, N₂, Ar, etc). Spare transport tubes are essential. The size of the tubes should be considered. Delivery rate trade offs exist between drive pressure, length and diameter of tube and viscosity of fluid. Very small bore tubing may have small dead volume, but may also require inordinately high pressures to push liquids from targets. Any contamination in the target material from irradiation could block very small bore tubing. Large tubes possess large dead volumes and require long transit times. Hence, significant radionuclide decay can occur during transport.

For most laboratories involved with F-18 and C-11 syntheses of clinical doses (average of 10 and 30 mCi respectively), transport between the radiochemistry lab and tomograph is easily accomplished by loading a dose into a shielded lead pig placed on a cart and wheeling the dose to the administration site (patient prep or tomograph room). This is not so easy for N-13 or O-15 agents. Significantly higher doses (average of 30 and 10 mCi respectively) are required for injection and mismatch between dose arrival and patient preparation. If O-15 steady-state studies are required, then batch transport is not really possible. Transport of radiopharmaceuticals is much less of a problem if all PET space is contiguous. Separation of cyclotron and radiochemistry from PET imaging will cause transport problems.

To overcome constraints of time and distance for dose delivery, a pneumatic rabbit transport system can be used. A spectrum of short (100 ft) and long (2 miles) transport systems are available. The dose is typically loaded into a 10 cc multidose vial which in turn is placed inside the rabbit (hollow pneumatic bullet). Air pressure is used to send the rabbit from the synthesis site, usually a hot cell, to the PET room. At the tomograph room the rabbit drops into a well shielded dose calibrator for radioactivity measurement and storage until needed. Easy open/close rabbits are essential to minimize hand dose to the technologists. The transport tube can be either polyethylene or metal, large diameter or small. If run for short distances, overhead access to the tube facilitates repair and in locating stuck rabbits. Underground locations, especially between buildings require that care be taken to minimize the number of turns, elevation changes, condensation, and collapse of the tube. In all cases, spare tubes should be included. Simple optical read outs are helpful for noting the progress of the rabbit during transport.

Simple, small bore (1-2 mm diameter) tubes are useful for transmitting O-15 agents from a cyclotron to a PET imager. Practical distances range from a few feet to about 2500 ft. Beyond that, significant problems begin to occur that cause dose spreading and dose loss because of decay during the transport. High transport rates can be used to overcome some of these problems, but a dose trapping mechanism must be instituted to capture the gas in the smallest volume possible and thereby keep the specific activity of the agent high. Failure to do so, for inhalation studies, results in O-15 activity being distributed in a volume that is incompatible with patient respiration. Include spares to permit immediate switch-over to a new tube if a failure is detected. Shield the tubes with material to stop positrons. Additional gamma shielding may be required if exposure rates are too high for particular areas above, below or near the path taken by the tubes.

RADIATION PROTECTION AND GENERAL SAFETY

Cyclotron

As previously discussed, the cyclotron self-shield or vault acts as the primary radiation protection device. Radiation exposures should be no greater than 2.0 mR/hr at the vault external surface or shield surface. Interlocks should be coupled to the manufacturer's systems to disable or shutdown cyclotron operation if conditions dictate unsafe conditions, such as separation of one of the shield components or an open vault door.

Radiation Monitoring

Multi-decade, continuous recording monitors should be located in the vault or cyclotron room, radiochemistry lab and PET imaging room. Similar monitors should be located in hot cell and shielded hood stacks. Data may be recorded by strip chart, but can be better viewed and condensed if acquired into a personal computer. All rooms that will contain radioactivity should also have room monitors with trip points and audible alerts. Several handheld survey meters should be available to measure local exposure rates or contamination. Alterations in rates or particularly high rates should be cross-checked with procedures to determine if personal doses can be subsequently lowered by altering procedures that utilize radioactive materials. Audible personnel monitors are helpful to continuously warn staff of high exposure situations (radiochemistry, cyclotron maintenance).

Storage of Radioactive Materials

Some radioactive waste will be generated daily that consists of synthesis waste (gloves, pipettes, syringes, vials) and PET study waste (blood, syringes, vials). This waste should be held for a day to allow for decay and then released for general pick-up. All too often, low level waste is placed into the trash and alarms are triggered in the trash compactors.

Longer lived materials may be present from target foil replacement, deflector replacement or other cyclotron/target maintenance procedures. Storage for these materials may be built into the vault wall or a cabinet located on an appropriate wall in the self-shielded cyclotron room. Some of the half-lives for these materials may be 6 months or longer, and may have exposure rates of 10-100 R/hr on contact.

Various phantoms for PET scanner QA are necessary. They may be filled with Ge-68 ($t_{1/2}=280$ days) and water. Storage of these sources within the PET tomograph room is best. A lead shielded cabinet reduces personnel exposure and cuts down singles background count rates for the tomograph. All phantoms should reside in a container to minimize the spreading of radioactivity in the event that a phantom develops a leak.

Safety

Eye glasses should be worn in all labs, but particularly in those areas where exposure to positrons are possible. Damage to the lens of the eye can be avoided if the positrons are absorbed by safety glasses.

Overall radiation exposure to personnel is minimized by shielding, by limiting access to radioactive materials and by increasing distance between staff and source of radiation. Shielding in procedure room walls is appropriate. Note that the half value layer for the annihilation radiation (511 keV) is 5 mm (0.2in) of lead. Use shielding around dose storage areas, and transport lines. Plan your facility to take advantage of exterior walls that use earth shielding. Rotate the responsibilities of technicians and technologists so as to distribute the dose burden. Perform radiopharmaceuticals syntheses in hot cells or behind movable shielding to limit hand doses. Develop automated/remote operation of handling doses prior to injection.

Security

Resign the PET center to limit or control general public access to potentially hazardous areas. Do not locate the PET center in a public access hallway that serves as a general escape route during emergencies such as fire. Limit key distribution and use a master, sub-master, individual key system to protect individuals by restricting access. This is extremely important if students are involved in research activities. Discuss your needs with housekeeping to minimize radiation exposure problems, indicate the need to overlap housekeeping activities when key personnel are present to discuss daily concerns and have a routine system to lock the area when no personnel are present. Staff often work late in the evening in research centers, therefore, institute a security and walk-through to be sure no accidents have occurred. Define procedures that personnel would follow in case of radiation spill, electrical hazard, water spill, power outage or fire.

PERSONNEL

The personnel requirements to run a PET Center are described below. Table 2 lists personnel needed for each category of PET center described in Table 1.

Engineers

Technical help is needed for in-house maintenance of the cyclotron and PET scanner. These individuals may also participate in computer hardware maintenance and expansion. Expertise in mechanical shop use for fabrication and repair is essential in the research environment. PET experience is extremely valuable.

Nurse

For routine clinical and extremely invasive PET procedures, a nurse is needed to prep patient, coordinate outpatient services, monitor vital signs and assist in patient/family education.

Physicists

PET physicists with a Ph.D. in nuclear or medical physics provide expertise in a number of ways. As with the radiochemist, they may have responsibility over the entire PET center. Their duties include implementing changes and improvements in tomograph design, as well as directing QA for the PET tomograph. They are responsible for cyclotron upkeep and new target designs. They also provide health physics support in the absence of a suitable institutional program.

Physicians

The role of the physician in PET is varied. They may direct the center. For routine, high throughput clinical sites, their role is much like that of a nuclear medicine physician. In research settings they provide significant input on the design of studies and analysis of data. They participate in clinical interpretation of scans, patient care, patient and volunteer referrals and recruitment, and obtain informed consent. PET experience is invaluable in moving the center toward its overall goals.

Programmers/Modelier

The programming tasks in PET are very large. They include increasing software performance, code validation, new applications development, and implementing a good user interface. System management must still be performed in distributed computer environments. The mathematics of PET modeling are well developed. The mechanics and speed improvements are still under development and require expertise to facilitate the need to analyze large quantities of data in short periods of time. Statistics for research studies will be handled by these individuals.

Radiochemists

Individual with Ph.D. in some form of chemistry, preferably medicinal, organic, or analytical chemistry with experience in PET labeling is required. Radiochemists may be in charge of the entire PET center, but certainly direct research and routine radiopharmaceuticals production, which may also include targetry and cyclotron operations. The radiochemist is in charge of all radiopharmaceuticals QA, and coordinates acquisition of IND (investigative new drug application). They design and direct biodistribution studies.

Radiochemistry Technicians

These individuals are responsible for running automated radiochemistry syntheses, performing nonstandard syntheses and for keeping daily QA records. They assist in precursor preparation and general chemistry laboratory upkeep. Qualified technicians may also help to devise black box technology for new syntheses. They also participate in biodistribution studies.

Radiopharmacists

In the absence of a radiochemist, as is possible in a category I Clinical PET center, a radiopharmacist may act to prepare automated doses and perform QA. This individual also helps in IND preparation following FDA guidelines, sterility testing, pyrogen testing and in ensuring that good laboratory practice is followed.

Secretaries and Receptionists

Staff are needed to maintain records, coordinate multiple procedures, and oversee outpatient recruiting. Personnel are also needed to prepare documents, enter database information, prepare grants, monitor phone calls and keep PET center staff schedules.

Students, Post Docs, Residents, Fellows

If education is a major component of the institutional goals, then it becomes important to provide that experience in the PET setting. This applies for graduate students in basic and clinical sciences, student technologists, and post doctoral scholars. Physician training is limited in PET. Advanced PET teaching programs in appropriate institutions will serve to train people for careers in a field which currently has few centers dedicated to train PET scientists.

Technologists

At least two (2) technologists are needed per PET scanner, Their role is to greet patients, educate patient and family, position patient, inject PET agent, perform PET study, work-up data, draw ROI's on PET images, archive data, participate in study design, insure adherence to study protocol, and operate cyclotron and automated radiochemistry systems if necessary. They should also perform arterial cauterization for withdrawing blood and determine radioactive metabolic components of arterial blood samples.

Table 2. Personnel Requirements

Personnel	Categories *			
	I	II	III	IV
Engineer	-	1/2	1/2	1
Nurse	1	1/2	1/2	1/2
Physician	1	1	1	1
Programmer/Modeler	-	-	1/2	1
Radiochemist	-	1	1	2
Radiochemistry Technician	-	1/2	1	2
Radiopharmacist	1	1/2	1/2	1/2
Receptionist	1	1	1	1
Secretary	-	-	1/2	1
Technologist	2	2	2	2
Total full-time employees	6 1/3	8	9 1/2	13

*See Table I for categories.

MAINTENANCE

Maintenance is required on all equipment in the PET center. The vendor will support the cyclotron, tomography and related systems at approximately 10% of the initial capital investment cost. Generic computer systems and operating system software can be subcontracted through the tomograph vendor or directly through the computer vendor (the latter usually being less expensive). The cyclotron and tomograph require regular maintenance. New systems require less, but still require some. Plan to give time to maintenance procedures on a regular basis. Monday mornings are the best, since the cyclotron is usually not used on weekends and residual activation of components can decay away during the weekend.

In research settings, self-maintenance often pays for itself by providing first-line service with in-house personnel who can go directly to the problem. Having an adequate supply of in-house spare parts and tools is essential for this service to work. In-house people should be factory trained and hired prior to the equipment arriving on site. Complete mechanical drawings, schematics and documentation are required. Adequate workspace to repair equipment must be provided. It often takes about 10-12 months for new maintenance staff to be thoroughly familiar with PET equipment. Plan for this learning process to occur during the start up phase and not when high patient throughput is desired.

SUMMARY

No two PET centers are alike. Therefore, the requirements and planning process for designing and building individual PET centers will not be identical. However, each must essentially ask and subsequently answer questions regarding the scope of the PET program and how best to achieve program goals. The plans for the PET center design should factor in the program goals and expectations. By spending adequate time in the planning stage, fewer problems will be encountered in the development of a new PET center.

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